UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended **December 31, 2022**

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission File Number: **001-36329**

Societal CDMO, Inc.

(Exact name of registrant as specified in its charter)

Pennsylvania	**26-1523233**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1 E. Uwchlan Ave, Suite 112, Exton, Pennsylvania	**19341**
(Address of principal executive offices)	(Zip Code)

(770) 534-8239

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol	Name of exchange on which registered
Common Stock, par value $0.01	**SCTL**	**The NASDAQ Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

On the last business day of the most recently completed second fiscal quarter, the aggregate market value (based on the closing sale price of its common stock on that date) of the voting stock held by non-affiliates of the registrant was $42.2 million.

As of February 22, 2023, there were 84,892,194 shares of common stock, par value $0.01 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K incorporates certain information by reference from the registrant's proxy statement for the 2023 annual meeting of shareholders to be filed no later than 120 days after the end of the registrant's fiscal year ended December 31, 2022.

Auditor Name: KPMG LLP Auditor Location: Philadelphia, PA Auditor Firm ID: 185

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K and the documents incorporated by reference herein contain forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this Annual Report on Form 10-K or the documents incorporated by reference herein regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "will," "would" "could," "should," "potential," "seek," "evaluate," "pursue," "continue," "design," "impact," "affect," "forecast," "target," "outlook," "initiative," "objective," "designed," "priorities," "goal," or the negative of such terms and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements are based on assumptions and expectations that may not be realized and are inherently subject to risks, uncertainties and other factors, many of which cannot be predicted with accuracy and some of which might not even be anticipated.

The forward-looking statements in this Annual Report on Form 10-K and the documents incorporated herein by reference include, among other things, statements about:

- our estimates regarding expenses, future revenue, cash flow, capital requirements and timing and availability of and the need for additional financing;
- our ability to maintain or expand our relationships, profitability and contracts with our key commercial partners, including the impact of changes in consumer demand for the products we manufacture for our commercial partners;
- our ability to grow and diversify our business with new customers, including our ability to meet desired project outcomes with development customers, and the potential loss of development customers if they do not receive adequate funding or if their products do not obtain U.S. Food and Drug Administration, or FDA, approval;
- the extent to which the COVID-19 pandemic or health emergencies continue to disrupt our business operations and the financial condition of our customers and suppliers, including our ability to initiate and continue relationships with manufacturers and third-party logistics providers given recent supply chain challenges;
- the extent to which inflation, global instability, including political instability and any resulting sanctions, export controls or other restrictive actions that may be imposed by the U.S. and/or other countries against governmental or other entities may disrupt our business operations or our financial condition or the financial condition of our customers and suppliers;
- our ability to operate under the lending covenants under our credit agreement and to pay required interest and principal amortization payments when due;
- the performance of third-party suppliers upon which we depend for Active Pharmaceutical Ingredients, or APIs, various other direct and indirect materials, and other third parties involved with maintenance of our facilities and equipment;
- our ability to maintain and defend our intellectual property rights against third-parties;
- pharmaceutical industry market forces that may impact our commercial customers' success and continued demand for the products we produce for those customers;
- our ability to recruit or retain key scientific, technical, business development, and management personnel and our executive officers, including as a result of applicable state and federal vaccine mandates;
- our ability to comply with stringent U.S. and foreign government regulation in the manufacture of pharmaceutical products, including current Good Manufacturing Practice, or cGMP, compliance and U.S. Drug Enforcement Agency, or DEA, compliance and other relevant regulatory authorities applicable to our business; and
- our ability to realize the expected benefits of the IriSys acquisition.

We may not achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly under "Risk Factors," that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, collaborations or investments we may make. You should read this Annual Report on Form 10-K and the documents that we incorporate by reference herein completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements.

Solely for convenience, tradenames referred to in this Annual Report on Form 10-K appear without the ® symbol, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these tradenames. All trademarks, service marks and tradenames included or incorporated by reference in this Annual Report on Form 10-K are the property of their respective owners.

SUMMARY OF RISK FACTORS

The risk factors summarized below could materially harm our business, operating results and/or financial condition, impair our future prospects and/or cause the price of our common stock to decline. These are not all of the risks we face and other factors not presently known to us or that we currently believe are immaterial may also affect our business if they occur. Additional detail about these risks are included in Item 1A, "Risk Factors."

Material risks that may affect our business, operating results and financial condition include, but are not necessarily limited to, those relating to:

Risks Related to Our Business and Industry

- Our revenues are dependent on a small number of commercial partners, and the loss of any one of these partners, or a decline in their orders, may adversely affect our business.
- Our failure to obtain new customer contracts or renew existing contracts may adversely affect our business.
- Failure to obtain manufacturing components, supplies and related materials from third-party manufacturers, including due to supply chain disruptions and inflationary pressures on materials and labor, could affect our ability to manufacture and deliver our products and sustain our profitability.
- Unstable market and macroeconomic conditions may have serious adverse consequences on our business, financial condition, and stock price.
- The COVID-19 pandemic has negatively impacted, and may continue to negatively impact, our business operations and financial results.
- Our customers' failure to receive or maintain regulatory approval for product candidates or products, or our failure to maintain regulatory approvals for manufacturing, could negatively impact our revenue and profitability.
- We depend on spending and demand from our customers for our contract manufacturing and development services and any reduction in spending or demand could have a material adverse effect on our business.
- Our future profitability could decline if we cannot sustain current operating conditions, including maintaining our current facility and equipment utilization and product mix.
- Our manufacturing services are highly complex, and if we are unable to provide quality and timely services to our customers, our business could suffer.
- If the products we manufacture for our customers do not gain market acceptance, and if there are adverse changes in the healthcare industry, our business, results of operations and financial condition may suffer.
- Our operating results may fluctuate significantly, which could adversely impact our stock price.

- We have a history of losses. If we cannot achieve and maintain profitability and secure additional business, we may have to raise additional capital.

- We have incurred significant indebtedness, which could adversely affect our business.

- We operate in a highly competitive market and competition may adversely affect our business.

- Issues with product quality could have a material adverse effect upon our business, subject us to regulatory actions and cause a loss of customer confidence in us or our products.

- If we fail to meet the stringent requirements of governmental regulation in the manufacture of pharmaceutical products, we could incur substantial costs and a reduction in revenues.

- Technological change may cause our offerings to become obsolete over time. A decrease in our customers' purchases of our offerings could have a material adverse effect on our business, results of operations and financial condition.

- We may be adversely affected by natural disasters or other events that disrupt our business operations, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

- We may be subject to litigation or government investigations for a variety of claims, which could adversely affect our operating results, harm our reputation or otherwise negatively impact our business.

- Our future success depends on our ability to retain our key executives as well as to attract, retain and motivate other qualified personnel.

- We may acquire other assets or businesses, or form collaborations or make investments in other companies or technologies, that could have a material adverse effect on our operating results, dilute our shareholders' ownership, increase our debt or cause us to incur significant expense.

- Our employees, partners, independent contractors, consultants and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

- We have faced and may continue to face potential product liability claims, and, if successful claims are brought against us, we may incur substantial liability.

- Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

- The security of our information technology systems may be compromised in the event of system failures, unauthorized access, cyberattacks or a deficiency in our cybersecurity, and confidential information, including non-public personal information that we maintain, could be improperly disclosed.

- If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity, which could negatively affect our operating results and business.

- Our U.S. government contracts require compliance with numerous laws that may present additional risk and liability.

Risks Related to Our Intellectual Property

- Litigation involving patents, patent applications and other proprietary rights is expensive and time-consuming. If we are involved in such litigation, it could interfere with our business.

- Competitors can challenge the U.S. patents protecting our commercial partners' product candidates in connection with filing an ANDA for a generic version or a 505(b)(2) NDA for a modified version of our commercial partners' product candidates.

- We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

- Our ability to manufacture products for our commercial partners may be impaired if any of our manufacturing activities, or the activities of third parties involved in our manufacture and supply chain, are found to infringe patents of others.

Risks Relating to Our Securities

- The market price and trading volume of our common stock have been and may continue to be volatile, which could result in rapid and substantial losses for our shareholders.

- Some provisions of our charter documents and Pennsylvania law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our shareholders, and may prevent attempts by our shareholders to replace or remove our current management.

- We have a limited number of authorized shares of common stock available for issuance and will need to seek shareholder approval to amend our Second Amended and Restated Articles of Incorporation to effect an increase in the number of authorized shares of our common stock.

PART I

Item 1. Business

Overview

We are a bi-coastal contract development and manufacturing organization, or CDMO, with capabilities spanning pre-investigational new drug development to commercial manufacturing and packaging for a wide range of therapeutic dosage forms with a primary focus on small molecules. With an expertise in solving complex manufacturing problems, we are a leading CDMO providing development, end-to-end regulatory support, clinical and commercial manufacturing, aseptic fill/finish, lyophilization, packaging and logistics services to the global pharmaceutical market. In addition to our experience in handling DEA-controlled substances and developing and manufacturing modified-release dosage forms, we have the expertise to deliver on our clients' pharmaceutical development and manufacturing projects, regardless of complexity level. We do all of this in our three state-of-the-art facilities that, in the aggregate, total 145,000 square feet, in Gainesville, Georgia and San Diego, California.

We currently manufacture the following key products with our key commercial partners: Ritalin LA®, Focalin XR®, Verelan PM®, Verelan SR®, Verapamil PM, Verapamil SR and Donnatal liquids and tablets. We also support numerous development stage products.

Effective March 21, 2022, our name was changed to Societal™ CDMO, Inc. This name change is reflective of our corporate transformation that has taken place primarily as a result of our 2021 acquisition and successful integration of IriSys, LLC, or IriSys, a San Diego-based CDMO, into the organization. Additionally, this name change creates a clear and powerful brand that describes the company's capabilities and commitment to our people, clients, and the patients we ultimately serve. The evolution to Societal™ CDMO also afforded us the opportunity to create new mission and vision statements that are better aligned with our new organization. Our mission is to improve patient lives through client partnerships. Our vision is to be a premier, trusted CDMO by bringing tailored solutions to our clients while fostering engaging and rewarding careers for our people. The name change, and the new mission and vision statements each signifies our commitment as a CDMO within the industry.

Our manufacturing and development capabilities include product development from formulation through clinical trial and commercial manufacturing, and specialized capabilities for solid oral dosage forms, with specialization in modified release technologies and facilities to handle highly potent compounds and controlled substances, liposomes and nano/microparticles, topicals and oral liquids. In September 2022, we announced a new state of the art, aseptic fill/finish and lyophilization suite in our San Diego facility to further our goal of offering end-to-end solutions to our clients. In addition to providing manufacturing capabilities, we offer our customers clinical trial support including over-encapsulation, comparator sourcing, packaging, labeling, storage and distribution. We have a bi-coastal footprint from which to better serve clients within the U.S., as well as globally. In a typical collaboration between us and our commercial partners, we continue to work with our partners to develop product candidates or new formulations of existing product candidates. We also typically exclusively manufacture and supply clinical and commercial supplies of these proprietary products and product candidates.

Our Strategy

The CDMO market is large and growing and is expected to continue to expand as outsourced penetration is seen due to biotechnology and pharmaceutical companies outsourcing more of their operations. We believe companies, which include our customers and prospective customers, generally prefer fewer, higher quality suppliers with expertise in addressing their formulation and manufacturing challenges early in the development cycle. Our strategy for growth in this market includes executing segment-specific sales and marketing strategies; building stronger visibility and an updated identity for the organization; enhancing both our customers' and employees' experience working with and for the company; and continuing to achieve growth and strengthen our financial position. This strategic mission is comprised of five key objectives:

- *Market Segmentation & Corporate Identity*. We have aligned our sales strategy to best serve each of three specific market segments that we currently support: (i) commercial oral solid dose products, including commercial tech transfer; (ii) our legacy profit-sharing products such as Verapamil; and (iii) early-stage development clients that represent a growing segment of our business. Our strategy calls for the development and execution of specific, targeted sales strategies for each segment. The decision-making processes, key drivers and metrics of success, project and product life-cycle management, and the approach to creating productive relationships with our clients are different enough for each of these three segments that we believe using this differentiated and focused approach is most effective for our customer base and our ability to optimize our operational and resource prioritization. With this strategic shift, we have seen good momentum with a growing sales pipeline in 2022. This change also allows Societal to have a more focused management of legacy programs as outlined above. Lastly, the successful rebranding of the company to Societal™ CDMO, and the adoption of our tag line, "Bringing Science to Society," helps us improve our identity and brand strength as a true CDMO partner in the biopharma market. With this brand evolution, we continue to effectively communicate our commitment as a partner to our clients as well as to our people, both present and future.

- *Capabilities Optimization and Expansion*. We continue to work to optimize our organizational structure and expand our capabilities. During 2022, we launched our new aseptic fill/finish and lyophilization services and recently expanded our filling and lyophilization capabilities to include biologics. We have created and expect to continue to expand strong synergies and efficiencies in our sales and marketing, quality and regulatory systems, human resources and people engagement practices, environmental health and safety policies, business systems and operational excellence processes. We plan to also continue to enhance our current capabilities and expand our operations to accommodate our growing customer base and attract new customers. We are structuring our organization to ensure execution and delivery of success including identifying opportunities for automation and digitalization of processes and ways of working. We also plan to expand our capabilities by identifying additional acquisition or expansion opportunities to broaden our offerings and grow our base of business.

- *Client Experience and Trust.* While we have long enjoyed our reputation as a high-quality partner, we believe that there is always room to improve. It is our goal to strengthen our client interactions, create unparalleled trust and establish valuable partnerships from process development through commercialization. This incorporates a multi-level contract approach which helps strengthen client relationships. During 2022, we introduced the launch of our new 20/80 Second Source Technical Transfer service for our commercial solid oral dose customers. Our team created this new service model in response to the growing risks and vulnerabilities associated with the global supply chain that have significantly elevated the importance of second source suppliers within the pharmaceutical industry. It is also important that, where it makes sense, we harmonize the experience our clients have at each of our sites. We have effective approaches to client communications and project management and want to deploy those approaches consistently across our organization. Additionally, we have adapted a new sales and proposal writing process, with the goal of streamlining the RFP process. All of the changes have been positively received by our clients. While we continue to make great strides with our customer experience, we intend to further improve their overall experience with Societal.

- *Employee Experience and Culture.* We aspire to establish an industry-leading employee experience and corporate culture of support, growth and professionalism that allows our employees not only to work but to thrive. During 2022, Societal CDMO was certified by Great Place to Work in the United States. As our employees drive our success, it is our goal to create an inspiring, flexible and rewarding experience for everyone at our company. In doing so, we believe we will strengthen both recruitment, employee engagement and retention, leading to a better workplace, better performance and better outcomes for our clients and for our company's financial performance.

- *Financial Strength.* We will continue to take steps to improve our financial strength. In 2022, successfully executed a multi-step strategy to recast our capital structure, improve our balance sheet and strengthen our overall financial profile. Specifically, we repaid and retired a $100.0 million debt facility with Athyrium financed through a sale and leaseback of our Gainesville, Georgia manufacturing site and campus, a sale of common and preferred stock and a new debt facility for $36.9 million from Royal Bank of Canada. We also signed an agreement to sell approximately 121 acres of land for $9.1 million. Combined, these transactions were advantageous to Societal CDMO with respect to debt leverage, maturity and interest. We will continue to carefully manage our cash, work to further reduce our debt, and engage in a consistent and transparent fashion with the investment community.

Our Competitive Strengths

We believe that the strong relationships we have with our commercial partners result from of our competitive strengths. In particular:

- *Our Operational Excellence*. We maintain a commitment to continually improve productivity and customer service levels and maintain excellent quality and regulatory compliance systems. We measure our operational excellence using industry-standard performance indicators such as our on time, in full delivery rate. We believe that our strong historical track record for operational excellence differentiates us from our competitors.

- *Focus on Specialized Markets*. We participate in specialized markets where significant technical expertise provides a competitive advantage. This includes differentiated drug delivery, controlled substance and complex formulation. One of our core areas of expertise is modified release oral solid dosage form development and manufacturing and custom release profile development, including for DEA controlled substance products. We developed extended, controlled and sustained release mechanisms for several current commercial products.

- *Our Longstanding Relationships with Our Partners*. We continue to maintain longstanding, collaborative relationships with our customers. We believe this allows us to leverage our extensive experience and deep knowledge of their business to better address our commercial partners' business and developmental goals.

- *Our Integrated Full-Service Development and Manufacturing Facilities*. We believe pharmaceutical companies generally prefer to engage with CDMOs that are able to work with a product throughout its lifecycle and have experienced a reliable track record of regulatory compliance and quality control first-hand. Our early-stage development and high-potency business feeds clinical and commercial manufacturing opportunities to our manufacturing business. We believe that by providing customers with a broad range of services from benchtop through commercial launch and supply, we can best support the needs of our customers throughout the lifecycle of their products. We provide fully integrated and customized biomanufacturing services that support our customers from the early preclinical stage through commercial launch and supply. Our services are all supported by modern facilities designed to meet customer needs from early-stage development to commercial supply.

- *Our Customer-Centric, Consultative Approach.* We are highly collaborative throughout the product lifecycle, guiding our commercial partners through the development process towards commercialization, including support and guidance on regulatory matters and chemistry, manufacturing and controls, or CMC, regulatory document preparation. In particular, we provide differentiated capabilities across a broad array of services that support the ability to serve our commercial partners through the entire development spectrum.

Services

We offer integrated solutions for formulation development, analytical method development, pharmaceutical manufacturing, regulatory support, and pharmaceutical packaging and logistics of both commercial and development stage products with a primary focus in the area of small molecules. Our facilities are located on both coasts of the United States and include:

- A 97,000 square foot manufacturing facility in Gainesville, Georgia that provides a full range of manufacturing capabilities from scale-up services to commercial manufacturing;

- A 24,000 square foot cGMP development and high-potency product facility in Gainesville, Georgia that focuses on development and clinical packaging; and

- A 24,500 square foot development facility in San Diego, California that focuses on development of advanced dosage forms (aseptic fill/finish, lyophilization and inhalation, etc.).

Our end-to-end service capabilities allow our customers to start with us for early-phase projects and stay with us through late phase and commercial projects. Early-stage coordination with customers utilizing our development and high-potency product facilities help assure streamlined technology transfer for final scale up and manufacturing at our commercial manufacturing site. Our capabilities include:

- *Formulation development*: Our formulation services support the development of a range of pharmaceutical products and advanced dosage forms. We have expertise in complex formulations, reformulation, physical characterization and excipient compatibility. We also conduct feasibility studies, identify critical variables and inefficiencies and optimize process.

- *Analytical methods development*: We offer diverse analytical services designed to assess quality. Our advanced facilities offer a full range of analytical testing capabilities, including product testing, ICH stability, method development and validation, chromatography and spectroscopy equipment, stability chambers and microbial testing.

- *Pharmaceutical manufacturing*: We can serve clients from small, early-phase batches to clinical and commercial production. We offer structured tech transfer services and key technologies including milling, blending, compression, spray and rotary granulation, particle and bead coating, encapsulation, liquids, lyophilization and sterile fill and finish.

- *Regulatory support*: We have extensive experience across all steps of the drug approval process. Our regulatory support services include handling communications with the FDA on behalf of our sponsor companies and consultation and guidance for client FDA meetings and responses. We utilize industry best practices including standardized reports for eCTD submission and pharmacovigilance reporting support.

- *Pharmaceutical packaging and logistics*: We offer contract packaging and logistics to maintain the safety and integrity of our customers' products. Our commercial-scale, single-line packaging operation has an annual maximum capacity of 2.5 million bottles per shift and can also serve late-phase clinical and development packaging needs. This line can package round or square bottles of various sizes and offers Drug Supply Chain Security Act, or DSCSA, compliant serialization services. We also offer smaller-scale primary and secondary packaging, labeling and kitting options suited for clinical trial materials and development packaging needs across a wide range of dosage forms.

Our Commercial Partners

We are party to agreements with each of our commercial partners governing the development, formulation and/or supply services we provide, as well as any applicable intellectual property licenses. Each commercial partner remains responsible for distributing, marketing and promoting their respective products. We are dependent on a small number of commercial partners, with our four largest customers (Teva Pharmaceutical Industries, Inc., or Teva, Novartis Pharma AG, or Novartis, Lannett Company, Inc., or Lannett, and InfectoPharm Arzneimittel und Consilium GmbH, or InfectoPharm) having generated 77% of our revenues for the year ended December 31, 2022, of which Teva generated 34%, Novartis generated 18%, Lannett generated 16%, and InfectoPharm generated 9%.

The table below details the key products developed and/or manufactured with our key commercial partners:

	Product	Indication	Territory	Revenue source	Agreement term
Teva	Verapamil SR	Hypertension	United States	Profit-sharing / manufacturing	Through December 31, 2024
Novartis	Ritalin LA®	Attention Deficit Hyperactivity Disorder	Worldwide, except Europe	Manufacturing	Through December 31, 2025
	Focalin XR®	Attention Deficit Hyperactivity Disorder	Worldwide, except Canada	Manufacturing	Through December 31, 2025
Lannett	Verelan PM® Verelan SR Verapamil PM	Hypertension	United States	Profit-sharing / manufacturing	Through December 31, 2024
Advanz	Donnatal liquids and tablets	Irritable bowel syndrome and acute enterocolitis	United States	Manufacturing	Through February 3, 2025
InfectoPharm	Ritalin LA®	Attention Deficit Hyperactivity Disorder	Europe	Manufacturing	Through April 30, 2025

Agreements with Key Commercial Partners

Teva

We are party to a License and Supply Agreement with Watson Laboratories, Inc., a subsidiary of Teva, or the Teva Agreement, pursuant to which we are the exclusive supplier of Verapamil SR to Teva. We own the authorized generic for Verapamil SR and, pursuant to the Teva Agreement, have granted Teva an exclusive license to commercialize and sell Verapamil SR in the United States. The Teva Agreement expires on December 31, 2024, after which it will renew for additional one-year periods unless terminated by either party. Under the Teva Agreement, Teva pays us a share of profits on sales of Verapamil SR.

Novartis

We are party to a Manufacturing and Supply Agreement with Novartis, or the Novartis Agreement, pursuant to which we continued our long-standing relationship with Novartis as the exclusive global supplier to Novartis of Ritalin LA and Focalin XR capsules. The Novartis Agreement has an original term expiring December 31, 2023, and will renew automatically thereafter for successive one-year periods unless terminated by either party at least 24 months prior. No notice of non-renewal has been delivered. Novartis may terminate the Agreement immediately if (i) any governmental regulatory authority prevents Novartis from supplying the active pharmaceutical ingredients in the products and/or exporting, purchasing or selling the products; (ii) any product cannot be reasonably commercialized for medical, scientific or legal reasons; or (iii) we fail to comply with certain health, safety and environmental protection requirements. After December 31, 2023, Novartis may terminate the Novartis Agreement upon 12 months' written notice in the event of any sale or divestment by us of our business or assets relating to the products. Novartis has provided us notice it intends to assign our agreement to Sandoz, its generic division, as part of the public spin-off of Sandoz.

Lannett

We are party to a License and Supply Agreement with Kremers Urban Pharmaceutical, Inc., a subsidiary of Lannett, or the Lannett Agreement, pursuant to which we supply Verelan PM and SR and Verapamil PM to Lannett. We own the new drug application, or NDA, related to Verelan and license commercialization rights to Lannett under the Lannett Agreement. The Lannett Agreement expires on December 31, 2024 and will renew thereafter for successive two-year periods. Under the Lannett Agreement, Lannett pays us a share of profits on sales of Verelan PM and SR and Verapamil PM. Lannett additionally pays us an annual license fee of $0.5 million and is obligated to reimburse to us 50% of the Prescription Drug User Act program fees associated with Verelan. In July 2022 we entered into an amendment to the Lannett Agreement pursuant to which we received improved overall economics, including a 10% increase in the profit share component of revenue from Verapamil PM product sales, as well as immediate and scheduled increases in manufacturing prices. Additionally, the amendment awarded us potential new GMP manufacturing agreements targeting injectable products for multiple additional Lannett development projects.

Advanz

We are party to an Amended and Restated Manufacturing and Supply Agreement with AmdiPharm Ltd., a subsidiary of Advanz Pharma Corp, Ltd. (collectively "Advanz"), pursuant to which we continued our multi-year relationship as the exclusive supplier of Donnatal to Advanz for sale in the United States. Under the agreement, we are Advanz's exclusive manufacturer of Donnatal and its authorized generic version until February 3, 2025. Both we and Advanz may terminate this Agreement for any reason at any time by giving the other party not less than twenty-four months prior written notice.

InfectoPharm

We are party to a Commercial Manufacturing and Supply Agreement with InfectoPharm Arzneimittel und Consilium GmbH, or InfectoPharm, pursuant to which we are the exclusive supplier to InfectoPharm of Ritalin LA capsules in Europe through December 31, 2023. The agreement has a term of three years, expiring April 30, 2025, and is subject to auto-renewal. Either we or InfectoPharm may elect not to renew this agreement by giving the other party at least one hundred eighty days prior written notice prior to the expiration of the agreement.

Backlog

Our backlog represents, as of a point in time, future revenue from work not yet completed under clinical and pre-clinical signed contracts. As of December 31, 2022, our backlog was approximately $24 million. While we anticipate the majority of our backlog will be recognized during fiscal year 2023, our backlog is subject to a number of risks and uncertainties, including but not limited to: the risk that a customer timely cancels its commitments prior to our initiation of manufacturing services, in which case we may be required to refund some or all of the amounts paid to us in advance under those canceled commitments; and the risk that a customer may experience delays in its program(s) or otherwise, which could result in the postponement of anticipated manufacturing services; the risk that we may not successfully execute on all customer projects, any of which could have a negative impact on our liquidity, reported backlog and future revenue and profitability.

Permits and Regulatory Approvals

We are required to comply with the regulatory requirements of various local, state, national and international regulatory bodies having jurisdiction in the countries or localities where we manufacture products or where our customers' products are distributed. In particular, we are subject to laws and regulations concerning research and development, testing, manufacturing processes, equipment and facilities, including compliance with cGMPs, labeling and distribution, import and export, and product registration and listing, and compliance with post-marketing reporting obligations. As a result, our facilities are subject to regulation by the FDA, as well as regulatory bodies of other jurisdictions in which we operate.

We hold various licenses and registrations for our manufacturing activities. The primary licenses and registrations held are FDA Registrations of Drug Establishments and DEA Controlled Substance Registration. Due to certain U.S. state law requirements, we also hold certain state licenses for distribution activities throughout certain states. We also hold cGMP certifications for European Union, or EU, importation of products made in Gainesville for sale in the EU and an ANVISA certification for sale in Brazil. Compliance with these licensing and regulatory requirements is a key aspect of our business and, if there are changes in the regulations applicable to our business in the United States or other jurisdictions, we may be required to obtain additional approvals or operate according to different manufacturing or operating standards or pay additional fees. This may require a change in our manufacturing techniques or additional capital investments in our facilities.

In certain of our commercial partnerships, our commercial partner is the product authorization holder for products that have been developed on behalf of the commercial partner. In other commercial partnerships, we are the authorization holder. When our commercial partner holds the relevant authorization from the FDA or other national regulator, we support this authorization by furnishing a letter of reference to the Drug Master File, or the chemistry, manufacturing and related data to the relevant regulator or sponsor to provide adequate manufacturing support in respect of the product. We generally update this information annually with the relevant regulator.

We hold the approved NDAs for Verelan SR and Verelan PM, which we license to Lannett and Teva, respectively. Verapamil SR and Verapamil PM are authorized generics.

Environmental and Safety Matters

Certain products manufactured by us involve the use, storage and transportation of toxic or hazardous material. Our operations are subject to extensive laws and regulations relating to the storage, handling, emissions, transportation and discharge of materials into the environment and the maintenance of safe working conditions. We maintain environmental and industrial safety and health compliance programs and training at our facilities.

Prevailing legislation tends to hold companies primarily responsible for the proper disposal of their waste even after transfer to third party waste disposal facilities. Other future developments, such as increasingly strict environmental, health and safety laws and regulations, and enforcement policies, could result in substantial costs and liabilities to us and could subject the handling, manufacture, use, reuse or disposal of substances or pollutants at our facilities to more rigorous scrutiny than at present.

Intellectual Property

The products we produce for our commercial partners are also typically covered by patents and patent applications owned by them. Although certain patents may have expired or may expire in the future, we believe there are other barriers to entry for our commercial partners and competition, including ownership of regulatory filings, NDAs, abbreviated new drug applications, or ANDAs, and drug master files, or DMFs, manufacturing trade secrets, proprietary dosage strengths, pricing limitations in various geographies, costs to revalidate with another supplier, maturity and life-cycle stage of products. We have acquired and developed and continue to acquire and develop knowledge and expertise and trade secrets in the provision of formulation, process development and manufacturing services. We intend to rely on a combination of patents and trade secrets, as well as confidentiality agreements and license agreements, to protect our proprietary know-how.

Competition

The contract development and manufacturing industry for pharmaceuticals is intensely competitive and highly regulated. Our current and future competitors include other CDMOs as well as segments of larger pharmaceutical, biotechnology and specialty pharmaceutical companies. Many of our competitors have greater financial and other resources than we have, such as more commercial resources, larger staff and more extensive marketing and manufacturing organizations.

We compete with other CDMOs such as Adare Pharma Solutions, Aenova Alcami, Avara Pharmaceutical Services, Corden Pharma, CoreRx, Pharmaceutics International, Quotient Sciences and Recipharm, segments of larger companies such as Patheon (a segment of ThermoFisher Scientific), Lonza and Catalent, as well as other development and manufacturing service providers.

Government Regulation

Governmental authorities in the United States at the federal, state and local level, and the equivalent regulatory authorities in other countries, extensively regulate the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, post-market reporting, promotion, distribution, marketing, export and import of prescription drugs, such as those we are developing and manufacturing. Any drug products developed or manufactured by us are subject to pervasive and continuing regulation by the FDA, including compliance with current Good Manufacturing Practices, or cGMP, which impose procedural and documentation requirements. The FDA or other regulatory agencies can delay approval of a drug if our manufacturing facilities are not able to demonstrate compliance with cGMPs, pass other aspects of pre-approval inspections (i.e., compliance with filed submissions) or properly scale up to produce commercial supplies. Drug manufacturers and their subcontractors, and those supplying products, ingredients and components of them, are required to register their establishments with the FDA and state agencies and are subject to periodic announced and unannounced inspections by the FDA and state agencies for compliance with cGMP and other regulations. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance. Failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal of product approval, recall or seizure of the product or other voluntary, FDA-initiated or judicial action that could delay or prohibit further operations.

The DSCSA added new sections to the Federal Food, Drug & Cosmetic Act, or FD&C Act, that require manufacturers, repackagers, wholesale distributors, dispensers, and third-party logistics providers to take steps to identify and trace certain prescription drugs to protect against the threats of counterfeit, stolen, contaminated, or otherwise harmful drugs in the supply chain. Among other mandates, the DSCSA requires manufacturers and repackagers to affix or imprint a unique product identifier (comprised of a standardized numerical identifier, lot number, and expiration date of the product) on certain prescription drug packages in both a human-readable and on a machine-readable data carrier. The standardized numerical identifier is comprised of the product's corresponding National Drug Code combined with a unique alphanumeric serial number. A drug product is misbranded if it does not bear the product identifier as required by Section 582 of the FD&C Act. Section 582 also established several requirements relating to the verification of product identifiers.

Certain products that we manufacture are regulated as "controlled substances" as defined in the Controlled Substances Act of 1970, or CSA, which establishes registration, security, recordkeeping, reporting, storage, distribution and other requirements administered and enforced by the DEA. The DEA is concerned with the control and handling of controlled substances, and with the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce. Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule.

The DEA regulates controlled substances by controlling them in five schedules. Schedule I and II controlled substances have a high potential for abuse, whereas Schedule III-V controlled substances have relatively decreasing potential for abuse. Therefore, the DEA imposes more stringent controls on Schedule I and II substances than Schedule III-V substances, including stricter security controls, quotas, and increased recordkeeping and reporting requirements. Certain of the products we manufacture and/or develop are regulated as Schedule II controlled substances. The DEA establishes annually an aggregate quota for how much certain controlled substances that we manufacture may be produced in total in the United States, based on the DEA's estimate of the quantity needed to meet legitimate scientific and medicinal needs. This limited aggregate amount that the DEA allows to be produced in the United States each year is allocated among individual companies, who must submit applications annually to the DEA for individual production and procurement quotas. We must receive an annual quota from the DEA in order to produce any Schedule II substance. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. In April 2018, the DEA proposed new guidelines aimed at strengthening the process for setting controls over diversion of controlled substances and making other improvements in the quota managements regulatory system for the production, manufacturing and procurement of controlled substances. Following a public comment period, the DEA published the final guidelines, which were substantially similar to the proposed guidelines, in July 2018. For 2019, the DEA proposed decreased manufacturing quotas for the six most frequently misused opioids, including hydrocodone, which we used in the manufacture of certain products, by an average of 10% as compared to the 2018 quotas. The DEA proposed further decreasing manufacturing quotas in 2020 for five of the six opioids, including hydrocodone, by an average of 28%. Together with reductions in morphine, this is a 53% decrease since 2016. In October 2019, the DEA proposed additional regulations to amend the manner in which the agency grants quotas to manufacturers. The proposed regulations, if finalized, would establish use-specific quotas, including commercial sales, product development, transfer, replacement, and packaging. To decrease the risk of diversion and increase accountability, inventory allowances would be reduced, and procurement quota certifications will be required. In April 2020, in response to the COVID-19 pandemic, the DEA adjusted the established 2020 aggregate production quotas and assessment of annual needs for select Schedule II substances. The DEA took this action to ensure that the country has an adequate and uninterrupted supply of these substances during the public health emergency. In November 2020, the DEA finalized further decreases to the quota for hydrocodone by 11.5%, which it had proposed in September 2020. In October 2021, the DEA proposed further decreases of 4% to the quota for hydrocodone for 2022. The DEA finalized the 2023 quotas in December 2022 and includes a 5% decrease for Schedule II opioids such as oxycodone and hydrocodone.

The DEA requires facilities that manufacture controlled substances to adhere to certain security requirements. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Required security measures include background checks on employees and physical control of inventory through measures such as cages, surveillance cameras and inventory reconciliations. Records must be maintained for the handling of all controlled substances and periodic reports must be made to the DEA, for example, distribution, acquisition, and inventory reports for Schedule I and II controlled substances, Schedule III substances that are narcotics and other designated substances. Reports must also be made for thefts or losses of any controlled substance and suspicious orders. In addition, special authorization and notification requirements apply to imports and exports.

The DEA requires drug manufacturers to design and implement a system that identifies suspicious orders of controlled substances, such as those of unusual size, those that deviate substantially from a normal pattern and those of unusual frequency, prior to completion of the sale. A compliant suspicious order monitoring, or SOM, system includes well-defined due diligence, "know your customer" efforts and order monitoring.

To enforce these requirements, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Individual states also independently regulate controlled substances. We are subject to state regulation of distribution for these products. Failure to maintain compliance with applicable requirements, particularly where noncompliance results in loss or diversion, can result in enforcement action that could have a material adverse effect on our business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations, or take other enforcement action. In certain circumstances, violations could result in criminal prosecution.

In addition to DEA regulations, the U.S. government and state legislatures have enacted legislation and regulations intended to fight the opioid epidemic. In February 2016, the FDA released an action plan to address the opioid epidemic, which is part of a broader initiative led by the Department of Health and Human Services, which includes the release of a new Guideline for Prescribing Opioids for Chronic Pain, FDA's requirement of enhanced warnings and safety labeling, and institution of a class-wide Risk Evaluation and Mitigation Strategy, or REMs, as a condition of approval. Further, the Comprehensive Addiction and Recovery Act, or CARA, was passed in 2016. CARA provides resources to improve state monitoring of controlled substances, including opioids. A Senate bill introduced in February 2018, known as CARA 2.0, would further limit initial prescriptions for opioids to three days, while exempting initial prescriptions for chronic care, cancer care, hospice or end of life care, and palliative care. CARA 2.0 would also increase civil and criminal penalties for opioid manufacturers that fail to report suspicious orders for opioids or fail to maintain effective controls against diversion of opioids. More recently, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, or Support Act, has been enacted. It provides for further regulation as well as funding for research and development of non-addictive painkillers. State legislatures have followed in the footsteps of the federal government in passing similar laws intended to limit prescription sales and quantities as well as increase the ability to monitor and regulate the manufacture and sale of opioids.

Corporate Information

We were incorporated under the laws of the Commonwealth of Pennsylvania in November 2007. Our principal executive offices are located at 1 E. Uwchlan Ave, Suite 112, Exton, Pennsylvania 19341 and our telephone number is (770) 534-8239.

Employees and Human Capital Resources

Employees

As of December 31, 2022, we had 275 full-time employees. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we believe our relationship with our employees is good.

Diversity & Inclusion

We are fundamentally committed to creating and maintaining a work environment in which employees are treated fairly, with dignity, decency, respect and in accordance with all applicable laws. We strive to create a professional work environment that is free from all forms of harassment, discrimination and bullying in the workplace, including sexual harassment and any form of retaliation. We are an equal opportunity employer and we strive to administer all human resources actions and policies without regard to race, color, religion, sex, national origin, ethnicity, age, disability, sexual orientation, gender identification or expression, past or present military or veteran status, marital status, familial status, or any other status protected by applicable law. Our management team and employees are expected to exhibit and promote honest, ethical, and respectful conduct in the workplace. All employees must adhere to a code of conduct that sets standards for appropriate behavior and are required to attend annual training to help prevent, identify, report, and stop any type of discrimination and harassment. Our recruitment, hiring, development, training, compensation, and advancement at our company is based on qualifications, performance, skills, and experience without regard to gender, race and ethnicity.

Competitive Pay & Benefits

We provide robust compensation and benefits programs to help meet the needs of our employees. In addition to salaries, these programs include potential annual discretionary bonuses, a 401(k) plan, healthcare and insurance benefits, flexible spending accounts, paid time off, various leave programs and flexible work schedules, among others. In addition, we offer every full-time employee, both exempt and non-exempt, the benefit of equity ownership in the company through stock option grants. We have also used targeted equity-based grants with vesting conditions to facilitate retention of personnel, particularly those with critical drug development skills and experience.

Safety

The safety, health and wellness of our employees is a top priority. In response to COVID-19, we implemented enhanced safety protocols including shift work scheduling to reduce number of people in the facility, requirements for the wearing of masks and for social distancing, increased cleaning procedures and readily available hand sanitizer. These protocols were designed to comply with health and safety standards as required by federal, state, and local government agencies, taking into consideration guidelines of the Centers for Disease Control and Prevention and other public health authorities. In addition, we have provided work-at-home arrangements for employees who are able to do so.

Available Information

Our website address is www.ir.societalcdmo.com. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, any amendments to those reports, filed or furnished with the Securities and Exchange Commission, or SEC, are available free of charge through our website. We make these materials available through our website as soon as reasonably practicable after we electronically file such materials with, or furnish such materials to, the SEC. The reports filed with the SEC by our executive officers and directors pursuant to Section 16 of the Exchange Act are also made available, free of charge on our website, as soon as reasonably practicable after copies of those filings are provided to us by those persons. These materials can be accessed through the "Investor" section of our website. The information contained in, or that can be accessed through, our website is not part of this Annual Report.

Item 1A. Risk Factors

The following risk factors and other information included in this Annual Report on Form 10-K should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Please see page 3 of this Annual Report on Form 10-K for a discussion of some of the forward-looking statements that are qualified by these risk factors. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. All references and risks related to the launch, commercialization or sale of any of our product candidates are predicated on such product candidates receiving the requisite marketing and regulatory approval in the United States and applicable foreign jurisdictions.

Risks Related to Our Business and Industry

Our revenues are dependent on a small number of commercial partners, and the loss of any one of these partners, or a decline in their orders, may adversely affect our business.

We are dependent on a small number of commercial partners, with our four largest customers (Teva Pharmaceutical Industries, Inc., or Teva, Novartis Pharma AG, or Novartis, Lannett Company, Inc., or Lannett, and InfectoPharm Arzneimittel und Consilium GmbH, or InfectoPharm) having generated 77% of our revenues for the year ended December 31, 2022, of which Teva generated 34%, Novartis generated 18%, Lannett generated 16%, and InfectoPharm generated 9%. If any one or more of these commercial partners faces increasing or new competition in their market, adjusts pricing, significantly reduces their purchasing volume or experiences financial difficulties such as bankruptcy, our revenues could be adversely affected.

Our profit sharing, royalty, and manufacturing revenues also depend on the ability of our commercial partners to effectively market and sell their products to their customers. A commercial partner may choose to devote its efforts to its other products or reduce or fail to devote the necessary resources to provide effective sales and marketing support for the products we manufacture and supply. Furthermore, the acquisition of or change in strategy by one of our customers could impact projects we are currently working on or planning to work on in the future. Our commercial partners face competition from other pharmaceutical companies for sales of products to end users. Competition from sellers of generic drugs is a major challenge for our commercial partners, and the loss or expiration of intellectual property rights for the products we manufacture can have a significant adverse effect on their sales volume and price. Our commercial partners have also experienced difficulties in recent years as the pharmaceutical industry was impacted by the COVID-19 pandemic, labor shortages, supply chain shortages, inflationary pressures and geopolitical turmoil. Such pressures could lead a partner to discontinue a product, make pricing changes or change ordering patterns. In addition, as pharmaceutical product pricing faces scrutiny by governments, legislative bodies and enforcement agencies, our commercial partners may lower their prices or adopt cost-savings measures which could be passed on to us or otherwise impact our profit-sharing revenues. Further, any commercial partner may divest the product we manufacture for them in whole or in certain markets, which may involve termination of our contract with such partner or the assignment of such contract to a new partner who may not be as effective at selling or commercializing such product. Pricing changes and any significant reduction, delay or cancellation of orders from our commercial partners could adversely affect our revenues.

Our failure to obtain new customer contracts or renew existing contracts may adversely affect our business.

Our agreements with Teva and Lannett expire on December 31, 2024, our agreement with InfectoPharm expires on April 30, 2025 and our agreement with Novartis expires on December 31, 2025. If any of these commercial partners fail to renew their contract, our revenues could be materially and adversely affected. We continually seek to renew existing customer contracts and secure new contracts, which subjects us to potentially significant pricing pressures. In the event we are unable to replace existing contracts in a timely manner or at all, or are forced to accept terms, including pricing terms, less favorable to us, our business, results of operations and financial condition could be materially and adversely affected.

Failure to obtain manufacturing components, supplies and related materials from third-party manufacturers, including due to supply chain disruptions and inflationary pressures on materials and labor, could affect our ability to manufacture and deliver our products and sustain our profitability.

We rely on third-party manufacturers to supply many of our manufacturing components, supplies and related materials, which in some instances are supplied from a single source. We also rely on our labor force to sustain our operations. Prolonged disruptions in the supply of any of our key manufacturing components, supplies and related materials, difficulty implementing replacement materials or new sources of supply; or a significant increase in the prices of manufacturing components, supplies and related materials or labor could have a material adverse effect on our operating results, financial condition or cash flows. In particular, manufacturing problems may occur with these suppliers, and if a supplier provides us with manufacturing components, supplies and related materials that are deficient or defective or if a supplier fails to provide us with such materials or supplies in a timely manner, we may have limited ability to find appropriate substitutes or otherwise meet required specifications and deadlines. Moreover, we could experience inventory shortages if we are required to use an alternative supplier on short notice, which also could lead to manufacturing components, supplies and related materials being purchased on less favorable terms than we have with our regular suppliers. If such problems occur, we may not be able to manufacture our products profitably or on time, which could harm our reputation and have a material adverse effect on our business.

For example, while the impact of COVID-19 has lessened in many ways, we are experiencing a higher level of residual supply chain disruptions that we are actively managing to meet our production timelines and that may constrain our ability to capture additional growth opportunities, beyond our established projections, from customers who would otherwise want to increase their safety stock of the products that we produce.

Several of our manufacturers and suppliers conduct business internationally. Travel bans and other restrictions may affect the ability of these companies to conduct commercial activity, which could disrupt our supply chain and negatively impact our operations. If our suppliers are unable to provide the products and manufacturing components necessary to conduct our business, we may experience inventory shortages, and could be required to use an alternative supplier on short notice and enter into agreements on less favorable terms than we have with our regular suppliers. We also rely on third parties for the maintenance of our facilities and equipment.

Unstable market and macroeconomic conditions may have serious adverse consequences on our business, financial condition, and stock price.

Global financial markets have recently and may continue to experience extreme volatility and disruptions, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability as a result of the COVID-19 pandemic, political unrest and other factors beyond control. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy and ability to raise capital may be adversely affected by any such economic downturn, volatile business environment, or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance, and stock price. In addition, there is a risk that one or more of our current customers, vendors or other partners may not survive these difficult economic times, which could directly affect our business.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. These fluctuations have often been unrelated or disproportionate to the operating performance of those companies. Further, the impacts of political unrest, including as a result of geopolitical tension, such as between the United States and China or the conflict between Russia and Ukraine, including any additional sanctions, export controls or other restrictive actions that may be imposed by the United States and/or other countries against governmental or other entities in, for example, Russia, also could lead to disruption, instability and volatility in the global markets, which may have an adverse impact on our business or ability to access the capital markets. Broad market and industry factors, including potentially worsening economic conditions and other adverse effects, political, regulatory, and other market conditions, may negatively affect the market price of shares of our common stock, regardless of our actual operating performance.

We continue to anticipate a general slowdown in clinical development activity as a result of clinical failures and/or a lack of adequate funding to go forward. We are making efforts to adapt to these market changes, including a reconfiguration of our business development team to be better positioned in the longer-term by focusing on account management roles and replacing

lost positions in strategic focus areas. The anticipated slowdown and/or the reconfiguration may cause a reduction in the number of business development opportunities that we will be able to pursue in 2023.

We expect to face continuing inflationary pressures on raw materials, labor and logistics during 2023. If inflation or other factors were to significantly increase our business costs, it may not be feasible to pass price increases on to our customers. Interest rates, the liquidity of the credit markets and the volatility of the capital markets could also affect our interest costs under our LIBOR-based term loan borrowings or our ability to access the capital markets. Any such increases in our costs or inability to access capital could have a material adverse effect on our business, results of operations and financial conditions.

The COVID-19 pandemic has negatively impacted, and may continue to negatively impact, our business operations and financial results.

Our sales and manufacturing operations for the year ended December 31, 2021 were disrupted as a result of the COVID-19 pandemic due to production slowdowns, stoppages and decreased demand for the products we manufacture, as well as broader economic efforts associated with the pandemic such as inflation, changes in laws and general volatility in the markets. There can be no assurance that our future results will not be impacted by lingering impacts from the COVID-19 pandemic or future global health emergencies as the effects of the disruption are still impacting several industries and future global health emergencies could have similar impacts.

Our customers' failure to receive or maintain regulatory approval for product candidates or products, or our failure to maintain regulatory approvals for manufacturing, could negatively impact our revenue and profitability.

Our business materially depends upon the regulatory approval of the products we manufacture. As such, if our customers experience a delay in, or failure to receive, approval for any of their product candidates or fail to maintain regulatory approval of products, our revenue and profitability could be adversely affected. Additionally, if the FDA or a comparable foreign regulatory authority does not approve of our facilities for the manufacture of a customer product or if it withdraws such approval in the future, our customers may choose to identify alternative manufacturing facilities and/or relationships, which could significantly impact our ability to expand our capacity and capabilities.

We depend on spending and demand from our customers for our contract manufacturing and development services and any reduction in spending or demand could have a material adverse effect on our business.

The amount that our customers spend on the development and manufacture of their products or product candidates, particularly the amount our customers choose to spend on outsourcing these services to us, substantially impacts our revenue and profitability. The outcomes of our customers' research, development and marketing also significantly influence the amount that our customers choose to spend on our services and offerings. Our customers determine the amounts that they will spend on our services based upon, among other things, the clinical and market success of their products, available resources, access to capital and their need to develop new products, which, in turn, depend upon a number of other factors, including their competitors' research, development and product initiatives and the anticipated market for any new products, as well as clinical and reimbursement scenarios for specific products and therapeutic areas. Due to economic developments related to COVID-19 and geopolitical conflicts, such as the conflict between Russia and Ukraine, which continue to have adverse effects on the U.S. and global markets, we anticipate a general slowdown in clinical development activity as a result of clinical failures and/or a lack of adequate funding to go forward, which may cause a reduction in the number of business development opportunities that we will be able to pursue during 2023. Recently, the pharmaceutical industry has experienced pressure with respect to access to capital, which may require some of our customers to limit their spending on research and development as they re-assess budgets. Further, increasing consolidation in the pharmaceutical industry may impact such spending, particularly in the event that any of our customers choose to develop or acquire integrated manufacturing operations. Any reduction in customer spending on development and related services as a result of these and other factors could have a material adverse effect on our business, results of operations and financial condition.

Our future profitability could decline if we cannot sustain current operating conditions, including maintaining our current facility and equipment utilization and product mix.

Our business is complex and depends upon a number of variables to sustain our profitability, including how well we leverage our fixed manufacturing costs and maintain our product sales mix.

We have incurred significant fixed costs to purchase equipment that supports our current and future customer base across a wide range of dosage forms and production scales. For example, in 2022, we launched a new state of the art, aseptic fill/finish and lyophilization suite in our San Diego facility to further our goal of offering end-to-end solutions to our clients. We depend on our workforce to operate our equipment, and we depend on customers to provide orders that will utilize our equipment. If we are not able to fully utilize our manufacturing capacity due to labor shortages, changes in customer or product mix, or changes in volume, our margins could be adversely affected. Further, there can be no assurance that our future revenue will be sufficient to ensure the economical operation of our facilities, in which case our results of operations could be adversely affected.

Some of our commercial products are significantly more profitable than others and may include profit-sharing, royalty or other forms of associated income. As a result, if we experience more growth in products that are less profitable than others, even if our revenues remain consistent or grow overall, we could become less profitable. Achieving and sustaining our profitability depends upon us experiencing a similar or more favorable mix of revenue, that will depend upon the nature of the different products and services that we offer and/or our customers' request. If we recognize less revenue from our most profitable products as a percentage of total revenue, our future profitability could be materially adversely impacted.

Our manufacturing services are highly complex, and if we are unable to provide quality and timely services to our customers, our business could suffer.

The manufacturing services we offer are highly complex, due in part to strict regulatory requirements. A failure of our quality control systems in our facilities could cause problems to arise in connection with facility operations for a variety of reasons, including equipment malfunction, viral contamination, failure to follow specific manufacturing instructions, protocols and standard operating procedures, problems with raw materials or environmental factors. Such problems could affect production of a single manufacturing run or a series of runs, requiring the destruction of products, or could halt manufacturing operations altogether. In addition, our failure to meet required quality standards may result in our failure to timely deliver products to our customers, which in turn could damage our reputation for quality and service. Any such incident could, among other things, lead to increased costs, lost revenue, reimbursement to customers for lost drug substance, damage to and possibly termination of existing customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other manufacturing runs. With respect to our commercial manufacturing, if problems are not discovered before the product is released to the market, we may be subject to regulatory actions, including product recalls, product seizures, injunctions to halt manufacture and distribution, restrictions on our operations, civil sanctions, including monetary sanctions, and criminal actions. In addition, such issues could subject us to litigation, the cost of which could be significant.

If the products we manufacture for our customers do not gain market acceptance, and if there are adverse changes in the healthcare industry, our business, results of operations and financial condition may suffer.

We depend on, and have no control over, consumer demand for the products we manufacture for our customers. Consumer demand for our customers' products could be adversely affected by, among other things, delays in regulatory review or approval, the inability of our customers to demonstrate the efficacy and safety of their products, the loss of patent and other intellectual property rights protection, the emergence of competing or alternative products, including generic drugs, the degree to which private and government payment subsidies for a particular product offset the cost to consumers and changes in the marketing strategies for such products. If the products we manufacture for our customers do not gain market acceptance, our revenues and profitability may be adversely affected.

We believe that continued changes to the healthcare industry, including ongoing healthcare reform, adverse changes in government or private funding of healthcare products and services, legislation or regulations governing the privacy of patient information or patient access to care, or the delivery, pricing or reimbursement of pharmaceuticals and healthcare services or mandated benefits, may cause healthcare industry participants to purchase fewer services from us or influence the price that others are willing to pay for our services. Changes in the healthcare industry's pricing, selling, inventory, distribution or supply policies or practices could also significantly reduce our revenue and profitability.

Our operating results may fluctuate significantly, which could adversely impact our stock price.

Our operating results may be subject to quarterly and annual fluctuations. Our operating results will be affected by numerous factors, including:

- fluctuations in the revenues, including the loss of a major commercial partner or product;
- the timing of purchasing order patterns, safety stock methodology and habits of our commercial partners;
- unsuccessful execution, postponement or cancellation of anticipated formulation, development and manufacturing services related to customer projects,
- variations in the level of expenses related to our production volumes and development programs;
- any intellectual property infringement lawsuit in which we may become involved;
- CDMO or pharmaceutical competitors that introduce new products or take increased positions that may emerge and reduce market share for our existing customer/partner products;
- our execution of any additional collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements;
- our acquisition, divestiture, spin-off or in-licensing of new technologies or assets.

Due to the various factors mentioned above, and others, the results of prior periods should not be relied upon as an indication of our future operating performance. If our operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

We have a history of losses. If we cannot achieve and maintain profitability and secure additional business, we may have to raise additional capital, which may not be on terms that are acceptable to us.

We have incurred losses of $19.9 million, $11.4 million and $27.5 million for the years ended December 31, 2022, 2021 and 2020, respectively. As of December 31, 2022, we had an accumulated deficit of $265.6 million. We have financed our operations through the issuance of debt and equity and through operations, and as of December 31, 2022, we had $41.3 million of outstanding indebtedness, $36.9 million of which was with Royal Bank of Canada. Although it is difficult to forecast all of our future liquidity requirements, we believe that our cash and cash equivalents on hand combined with our projected cash receipts from services generated under our customer contracts will be sufficient to fund our operations beyond one year after the date our financial statements included in this Annual Report on Form 10-K are issued. In addition, in the event a customer timely cancels its commitments prior to our initiation of manufacturing services, we may be required to refund some or all of the advance payments made to us under those canceled commitments, which would have a negative impact on our liquidity and future revenue.

In the event we are unable to maintain sufficient business to support our current operations, we may need to raise additional capital in the future. There can be no assurance that equity financing will be available on acceptable terms or at all. Our ability to raise additional capital in the equity markets to fund our future operations is dependent on a number of factors, including, but not limited to, the market demand for our common stock. The market demand or liquidity of our common stock is subject to a number of risks and uncertainties, including but not limited to, our financial results and economic and market conditions. In addition, even if we are able to raise additional capital, it may not be at a price or on terms that are acceptable to us.

We have incurred significant indebtedness, which could adversely affect our business.

As of December 31, 2022, we had outstanding indebtedness of $41.3 million. Our indebtedness could have important consequences to our shareholders. For example, it:

- increases our vulnerability to adverse general economic or industry conditions;
- limits our flexibility in planning for, or reacting to, changes in our business or the industries in which we operate;
- reduces proceeds we may receive as a result of any sale;

- makes us more vulnerable to increases in interest rates, as our largest debt instrument with Royal Bank of Canada is at a variable rate;

- limits our ability to obtain additional financing or refinancing in the future for working capital or other purposes; and

- places us at a competitive disadvantage compared to our competitors that have less indebtedness.

Any of the above-listed factors could materially adversely affect our business, financial condition, results of operations and cash flows. Our credit agreement with Royal Bank of Canada also contains certain financial and other covenants, including a minimum liquidity requirement and maximum leverage ratios and includes limitations on, among other things, additional indebtedness, paying dividends in certain circumstances, acquisitions and certain investments. The credit agreement provides for certain mandatory prepayment events, including with respect to the proceeds of asset sales, extraordinary receipts, debt issuances and other specified events, based on the terms of the credit agreement with Royal Bank of Canada. Any failure to comply with the terms, covenants and conditions of the credit agreement may result in an event of default under such agreement, which could have a material adverse effect on our business, financial condition and results of operation. Additionally, pursuant to a related security agreement between us and Royal Bank of Canada, we granted Royal Bank of Canada a security interest in substantially all of our assets to secure their obligations to Royal Bank of Canada under the credit agreement. The security interest granted over our assets could limit our ability to obtain additional debt financing.

We cannot assure you that our business will generate sufficient cash flow from operations or that future financing will be available to us in amounts sufficient to enable us to make required and timely payments on our indebtedness, or to fund our operations.

Our ability to close the sale of land adjacent to our Gainesville, Georgia manufacturing campus, or the Land Sale, is subject to several customary closing conditions, which may impact our ability to complete the Land Sale on the anticipated timeline or at all.

In September 2022, we signed a sales and purchase agreement related to the Land Sale, pursuant to which we agreed to sell approximately 121 acres of land adjacent to our Gainesville, Georgia manufacturing campus for expected proceeds of $9.1 million. We are obligated to use the proceeds of the Land Sale to repay outstanding balances under our credit agreement with Royal Bank of Canada. We expect to close the Land Sale in the second half of 2023; however, the closing of the Land Sale is subject to customary closing conditions for transactions of this type, including completion of title and environmental due diligence and receipt of certain zoning approvals and permits.

If the closing of the Land Sale does not occur within 12 months of closing under our credit agreement with Royal Bank of Canada, (i) the amortization percentages under the credit agreement will increase by an additional 0.625% for each installment due until such time as such real property is sold and the required payment is made to Royal Bank of Canada and (ii) we will be required to pay a fee equal to 1.00% of the original principal amount of the term loan.

Any delay in the closing of the Land Sale, or failure of the Land Sale to close at all, could have a material adverse effect on our results of operations, cash flows and financing condition, including as a result of the changes under our credit agreement with Royal Bank of Canada as set forth above.

We operate in a highly competitive market and competition may adversely affect our business.

We operate in a market that is highly competitive. Our competition in the contract manufacturing market includes full-service contract manufacturers and large pharmaceutical companies offering third-party manufacturing services to fill their excess capacity. We may also compete with the internal operations of those pharmaceutical companies that choose to source their product offerings internally. In addition, most of our competitors may have substantially greater financial, marketing, technical or other resources than we do. Moreover, additional competition may emerge, particularly in lower-cost jurisdictions such as India and China, which could, among other things, result in a decrease in the fees paid for our services, which may adversely affect our results of operations and financial condition.

Our business, financial condition, and results of operations are subject to risks arising from the international scope of our manufacturing and supply relationships.

Some of our customers source raw materials outside the United States. As such, we are subject to risks associated with such international manufacturing relationships, including:

- unexpected changes in regulatory requirements;

- problems related to markets with different cultural biases or political systems;
- longer payment cycles and shipping lead-times;
- increased risk relating to the transport of products internationally, including damage to our customers' API, shipment delays relating to the import or export of our products or the delivery of products by means of additional third-party vendors;
- difficulties importing or exporting supplies or products;
- unforeseen global instability, including political instability, geopolitical tension, such as between the U.S. and China or the conflict between Russia and Ukraine, including any additional resulting sanctions, export controls or other restrictive actions that may be imposed by the U.S. and/or other countries against governmental or other entities in, for example, Russia, or instability from an outbreak of pandemic or contagious disease (including, for example, the recent coronavirus outbreak);
- compliance with the U.S. Foreign Corrupt Practices Act and other laws and regulations governing international trade;
- changes to U.S. and foreign trade policies, including the enactment of tariffs on goods imported into the United States; and
- imposition of domestic and international customs and tariffs, withholding or other taxes, including any value added taxes.

Additionally, we are subject to periodic reviews and audits by governmental authorities responsible for administering import/export regulations. To the extent that we are unable to successfully defend against an audit or review, we may be required to pay assessments, penalties, and increased duties on products imported into the United States.

Issues with product quality could have a material adverse effect upon our business, subject us to regulatory actions and cause a loss of customer confidence in us or our products.

Our success depends upon the quality of our products. Quality management plays an essential role in meeting customer requirements, preventing defects, improving our customers' product candidates and services and assuring the safety and efficacy of their product candidates. Our future success depends on our ability to maintain and continuously improve our quality management program. A quality or safety issue may result in adverse inspection reports, warning letters, untitled letters, FDA Form 483s, product recalls or seizures, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions, costly litigation, refusal of a government to grant approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses. For example, in January 2023, the FDA completed an inspection of our San Diego facility and is expected to issue a Form 483 to us recommending an improvement to our building management system. An inability to address the Form 483 or any other quality or safety issue in an effective and timely manner may also cause negative publicity, a loss of customer confidence in us or our future products, which may result in difficulty in successfully launching product candidates and loss of sales, which could have a material adverse effect on our business, financial condition, and results of operations.

Our development and formulation services projects are typically for a shorter term than our manufacturing projects, and any failure by us to maintain an adequate volume of development and formulation services projects, including due to lower than expected success rates of the products for which we provide services, could have a material adverse effect on our business, results of operations and financial condition.

Our pharmaceutical development services business contracts are generally shorter in term than our manufacturing contracts and typically require us to provide development services within a designated scope. Since our development and formulation services focus on products that are still in developmental stages, their viability depends on the ability of such products to reach their respective subsequent development phases. In many cases, such products do not reach subsequent development phases and, as a result, the profitability of the related pharmaceutical development service project may be limited. Even if a customer wishes to proceed with a project, the product we are developing on such customer's behalf may fail to receive necessary regulatory approval or may have its development hindered by other factors, such as the development of a competing product.

If we are unable to continue to or timely obtain new projects from existing and new customers, our development and formulation services business could be adversely affected. Furthermore, although our development and formulation services business may act as a pipeline for our manufacturing services business, we cannot predict the conversion rate of our development and formulation services projects to commercial manufacturing services projects, or how successful we will be in winning new projects that lead to a viable product. As such, an increase in the turnover rate of our development and formulation services projects may not benefit our manufacturing services business at a later time.

In addition, our backlog is subject to a number of risks and uncertainties, including risk that a customer timely cancels its commitments, the risk that a customer may experience delays in its program(s) or otherwise, which could result in the postponement or cancellation of anticipated formulation, development and manufacturing services revenue. There is risk that our business development efforts may not materialize as quickly as we have projected, that we may not successfully execute on all customer projects, any of which could have a negative impact on our liquidity, reported backlog and future revenue. Further, the discontinuation of a project as a result of our failure to satisfy a customer's requirements may also affect our ability to obtain future projects from such customer, as well as from new customers. Any failure by us to maintain a high volume of development and formulation services projects could have a material adverse effect on our business, results of operations and financial condition.

If we fail to meet the stringent requirements of governmental regulation in the manufacture of pharmaceutical products, we could incur substantial costs and a reduction in revenues.

We are required to maintain compliance with cGMP and applicable product tracking and tracing requirements, and our manufacturing facilities are subject to inspections by the FDA and other global regulators to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending application(s) to the FDA and acceptance of the change by the FDA prior to release of our manufactured products. Because we produce multiple products at our manufacturing facilities, there are increased risks associated with cGMP compliance. We can provide no assurance that we will not encounter future inspections resulting in observations not acceptable by the FDA.

Our inability to demonstrate ongoing cGMP compliance could require us to engage in additional lengthy and expensive remediation efforts, withdraw or recall products and/or interrupt commercial supply of any products. Any delay, interruption or other issue that arises in the manufacture, fill/finish, packaging, or storage of any drug product as a result of a failure of our facilities to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our relationships with our commercial partners, which would substantially harm our business, prospects, operating results and financial condition. Any ongoing or additional findings of non-compliance could also increase our costs and cause us to lose revenue from manufactured products, which could be seriously detrimental to our business, prospects, operating results and financial condition.

Additionally, our manufacturing activities are subject to the Controlled Substances Act of 1970, or CSA, and the regulations of the DEA. Accordingly, we must adhere to a number of requirements with respect to controlled substances, including registration, recordkeeping and reporting requirements; labeling and packaging requirements; security controls, procurement and manufacturing quotas; and certain restrictions on refills. Failure to maintain compliance with applicable requirements can result in an enforcement action that could have a material adverse effect on our business, financial condition, operating results and cash flows. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In certain circumstances, violations could result in criminal proceedings.

Manufacturers of drug products and their facilities are subject to payment of substantial user fees and continual review and periodic inspections by the FDA and other regulatory authorities, including equivalent regulatory authorities in other countries, for compliance with cGMP regulations and adherence to commitments made in the NDA or the application for marketing authorization. If we, or a regulatory authority, discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with a facility where the product is manufactured, a regulatory authority may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market, suspension of manufacturing, or other FDA action or other action by the equivalent regulatory authorities in other countries.

If we use hazardous materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our operations involve the controlled use of hazardous materials and chemicals. We are subject to federal, state and local laws and regulations in the U.S. governing the use, manufacture, storage, handling and disposal of hazardous materials and chemicals. Although we believe that our procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we may incur significant additional costs to comply with applicable laws in the future. Even if we comply with applicable laws, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials or chemicals. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our contract manufacturing operations, which could materially harm our business, financial condition and results of operations.

We may not be able to successfully offer new services, which could have a material adverse effect on our business, results of operations and financial condition.

In order to successfully compete, we will need to offer and develop new services. Without the timely introduction of enhanced or new services, our services and capabilities may become obsolete over time, in which case, our revenues and operating results would suffer. The related development costs may require a substantial investment before we can determine their commercial viability, and we may not have the financial resources to fund such initiatives.

In addition, the success of enhanced or new services will depend on several factors, including but not limited to our ability to:

- properly anticipate and satisfy customer needs, including increasing demand for lower cost services;
- enhance, innovate, develop and manufacture new offerings in an economical and timely manner;
- differentiate our deliverables from competitors' offerings;
- meet quality requirements, authorization requirements, and other regulatory requirements of government agencies; and
- avoid infringing the proprietary rights of third parties.

Even if we were to succeed in creating enhanced or new services, those services may not result in commercially successful offerings or may not produce revenues in excess of the costs of development and capital investment and may be quickly rendered obsolete by changing customer preferences or by technologies or features offered by our competitors. In addition, innovations may not be accepted quickly in the marketplace due to, among other things, entrenched patterns of clinical practice, the need for regulatory authorization and uncertainty over market access or government or third-party reimbursement. If we are not able to offer new services and effectively compete, our business, financial condition, and results of operations could be negatively impacted.

Technological change may cause our offerings to become obsolete over time. A decrease in our customers' purchases of our offerings could have a material adverse effect on our business, results of operations and financial condition.

The healthcare industry is characterized by rapid technological change. Demand for our services may change in ways that we may not anticipate because of evolving industry standards or as a result of evolving customer needs that are increasingly sophisticated and varied or because of the introduction by competitors of new services and technologies. We may also need to purchase additional equipment, some of which can take several months or more to procure, install and validate, and increase or modify our manufacturing, maintenance, software and computing capabilities to meet changing demand. In addition, we require capital and resources to support the maintenance and improvement of our facilities, including replacing or repairing aging production equipment and updating overall facility master plans. If we are unable to maintain and improve our facilities, we may experience unscheduled equipment downtime and unpredicted machinery failure and become unable to supply our customers with products or services which may affect business continuity. Any such incident or disruption in business continuity could have a material adverse effect on our business, results of operations and financial condition.

We may be adversely affected by natural disasters or other events that disrupt our business operations, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our manufacturing facilities are located in Gainesville, Georgia and San Diego, California, where natural disasters or similar events, like hurricanes, blizzards, tornadoes, fires, floods, earthquakes or explosions or large-scale accidents or power outages, could severely disrupt our operations and have a material adverse effect on our business, prospects, results of operations and financial condition. If a disaster, power outage or other event occurred that prevented us from using all or a significant portion of our Gainesville and/or San Diego facilities, damaged critical infrastructures, such as manufacturing resource planning and enterprise quality systems, or otherwise disrupted operations at that location, it may be difficult or, in certain cases, impossible for us to continue our development, formulation and manufacturing business for a substantial period of time, which could have a material adverse effect on our business, financial condition, and results of operations.

Currently, we maintain insurance coverage against damage to our property and equipment, and to cover business interruption expenses, in an amount we believe is sufficient for our development, formulation and manufacturing operations. However, there can be no assurance that such insurance will continue to be available on acceptable terms or that such insurance will provide adequate protection against actual losses. Even if we maintain adequate insurance coverage, claims could have a material adverse effect on our financial condition, liquidity and results of operations and on our ability to obtain suitable, adequate or cost-effective insurance in the future.

We must comply with environmental and health and safety laws and regulations, which can be expensive and restrict how we do business.

We are subject to federal, state and local laws, rules, regulations and policies concerning the environment and the health and safety of our employees. We may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions, which could have a material adverse effect on our business, financial condition, and results of operations.

In addition, our business involves the use, generation and disposal of hazardous materials, including chemicals, solvents, agents and biohazardous materials. As a result, we are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. We cannot completely eliminate the risk of accidental contamination or injury from these materials. We currently contract with third parties to dispose of these substances that we generate, and we rely on these third parties to properly dispose of these substances in compliance with applicable laws and regulations. If these third parties do not properly dispose of these substances in compliance with applicable laws and regulations, we may be subject to legal action by governmental agencies or private parties for improper disposal of these substances. The costs of defending such actions and the potential liability resulting from such actions are often substantial amounts. In the event we are subject to such legal action or we otherwise fail to comply with applicable laws and regulations governing the use, generation and disposal of hazardous materials and chemicals, we could be held liable for any damages that result, and any such liability could exceed our resources. In addition, we may incur costs and expenses due to injuries to our employees, including those resulting from the use of hazardous materials; workers' compensation insurance may not provide adequate coverage against potential liabilities. If we become subject to any of the foregoing liabilities, our business, financial condition, and results of operations could be materially adversely impacted.

We may be subject to litigation or government investigations for a variety of claims, which could adversely affect our operating results, harm our reputation or otherwise negatively impact our business.

We may be subject to litigation or government investigations. These may include claims, lawsuits, and proceedings involving product liability, labor and employment, wage and hour, commercial and other matters. For example, we were subject to securities class action litigation as discussed in note 7 to our consolidated financial statements beginning on page F-1 of this Annual Report on Form 10-K that was settled in 2022. The outcome of any litigation or government investigation, regardless of its merits, is inherently uncertain. Any lawsuits or government investigations, and the disposition of such lawsuits and government investigations, could be time-consuming and expensive to resolve and divert management attention and resources. Any adverse determination related to litigation or government investigations could adversely affect our operating results, harm our reputation or otherwise negatively impact our business. In addition, depending on the nature and timing of any such dispute, a resolution of a legal matter or government investigation could materially affect our future operating results, our cash flows or both.

Our future success depends on our ability to retain our key executives as well as to attract, retain and motivate other qualified personnel.

We are highly dependent on the principal members of our executive team and, in particular, the services of J. David Enloe, Jr., our President and Chief Executive Officer, and Ryan Lake, our Chief Financial Officer, the loss of whose services would adversely impact the achievement of our objectives. We have entered into employment agreements with each of our executive officers. Recruiting and retaining qualified employees for our business, including business development, scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. The inability to recruit or loss of the services of any executive or key employee could impede the progress of our business development, manufacturing, quality, growth and diversification objectives.

We may acquire other assets or businesses, or form collaborations or make investments in other companies or technologies, that could have a material adverse effect on our operating results, dilute our shareholders' ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of assets, including, businesses or strategic alliances and collaborations, to expand our existing technologies and operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any such transaction, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. Integration of an acquired company or assets may also disrupt ongoing operations, require the hiring of additional personnel and the implementation of additional internal systems and infrastructure, especially the acquisition of commercial assets, and require management resources that would otherwise focus on developing our existing business.

To finance any acquisitions or collaborations, we may choose to issue debt or shares of our common or preferred stock as consideration. Any such issuance of shares would dilute the ownership of our shareholders. If the price of our common stock is low or volatile, we may not be able to acquire other assets or companies or fund a transaction using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are acceptable to us, or at all.

Our employees, partners, independent contractors, consultants and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, partners, independent contractors, consultants and vendors may engage in fraudulent or other illegal activity with respect to our business. Misconduct by these employees, partners, independent contractors, consultants and vendors could include intentional, reckless and/or negligent conduct or unauthorized activity that violates: (1) FDA or DEA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA; (2) manufacturing standards; (3) federal, state and foreign healthcare fraud and abuse laws and regulations; or (4) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. Any incidents or any other conduct that leads to an employee receiving an FDA debarment could result in a loss of business from our partners and severe reputational harm. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business, operating results and financial condition.

We have faced and may continue to face potential product liability claims, and, if such claims are successful, we may incur substantial liability.

The use of our products exposes us to the risk of product liability claims as well as potential toxic tort and other types of product liability claims that are inherent in the manufacture of pharmaceutical products. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and negative media attention;
- withdrawal of our customers clinical study participants or adverse effects occurring during such clinical trials;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- decreased demand for our manufacturing services or loss of any of our commercial partners;
- substantial monetary awards to patients or other claimants;
- the inability of our customers to commercialize their product candidates, if approved; and
- increased scrutiny and potential investigation by, among others, the FDA, the Department of Justice, the Office of Inspector General of the U.S. Department of Health and Human Services, State Attorneys General, members of Congress and the public.

Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2022, we had federal and state net operating loss carry forwards, or NOLs, of approximately $125.6 million and $135.4 million, respectively. The federal carry forwards for 2008 through 2017 will expire in 2028. Federal net operating losses incurred in 2018 and onward have an indefinite expiration under the 2017 Tax Cut & Jobs Act. The state carry forwards, including those generated in 2022, will expire in 2028 through 2042. A full allowance for the value of the NOLs is provided for in our consolidated financial statements as of December 31, 2022. We cannot guarantee what the ultimate outcome or amount of the benefit we may receive from the NOLs, if any, will be.

The security of our information technology systems may be compromised in the event of system failures, unauthorized access, cyberattacks or a deficiency in our cybersecurity, and confidential information, including non-public personal information that we maintain, could be improperly disclosed.

We rely extensively on information technology and systems including internet sites, data hosting, physical security, and software applications and platforms. Our information technology systems, some of which are managed by third parties, may be susceptible to damage, disruptions or shutdowns due to computer viruses, attacks by computer hackers, failures during the process of upgrading or replacing software, power outages, user errors or catastrophic events. A significant breakdown, invasion, corruption, destruction or interruption of critical information technology systems, by our employees, others with authorized access to our systems or unauthorized persons could negatively impact or interrupt operations. For example, the loss of data from completed or ongoing clinical trials for product candidates could result in delays in regulatory approval efforts and significantly increase our costs to recover or reproduce the data. The use of technology, including cloud-based computing, creates opportunities for the unintentional dissemination or intentional destruction of confidential information stored in our systems or our third-party systems. We could also experience a business interruption, theft of confidential information or reputational damage from malware or other cyberattacks, which may compromise our systems or lead to data leakage, either internally or at our third-party providers.

As part of our business, we maintain large amounts of confidential information, including non-public personal information on our employees. The maintenance of such information is governed by various rules and regulations in the jurisdictions in which we conduct our business, including by the General Data Privacy Regulation, or GDPR, in the European Union. Breaches in security, either internally or at our third-party providers, could result in the loss or misuse of this information, which could, in turn, result in potential regulatory actions or litigation, including material claims for damages, interruption to our operations, damage to our reputation or otherwise have a material adverse effect on our business, financial condition and operating results. Our information security policies and systems may not prevent unauthorized use or disclosure of confidential information, including non-public personal information.

Any such business interruption, theft of confidential information or reputational damage from malware or other cyberattacks, or violation of personal information laws, could have a material adverse effect on our business, financial condition, and results of operations.

If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity, which could negatively affect our operating results and business.

We may be subject to laws and regulations that address privacy and data security of patients who use our customers' products in the United States and in states in which we conduct our business. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act) govern the collection, use, disclosure, and protection of health-related and other personal information. For instance, the Health Insurance Portability and Accountability Act, or HIPAA, imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information and imposes notification obligations in the event of a breach of the privacy or security of individually identifiable health information on entities subject to HIPAA and their business associates that perform certain activities that involve the use or disclosure of protected health information on their behalf. Failure to comply with applicable data protection laws and regulations could result in government enforcement actions and create liability for us, which could include civil and/or criminal penalties, as well as private litigation and/or adverse publicity that could negatively affect our operating results and business.

Our U.S. government contracts require compliance with numerous laws that may present additional risk and liability.

We provide services to the National Institutes of Health, a part of the U.S. Department of Health and Human Services. As a result, we must comply with certain laws and regulations relating to the award, administration, and performance of U.S. government contracts. U.S. government contracts typically contain a number of extraordinary provisions that would not typically be found in commercial contracts and which may create a disadvantage and additional risks to us as compared to competitors that do not rely on government contracts. As a U.S. government service provider and subcontractor, we are subject to increased risks of investigation, audit, criminal prosecution, and other legal actions and liabilities to which purely private sector companies are not. The results of any such actions could adversely impact our business and have an adverse effect on our financial performance.

Additionally, a violation of specific laws and regulations could result in the imposition of fines and penalties or the termination of our contracts, as well as suspension or debarment. The suspension or debarment in any particular case may be limited to the facility, contract or subsidiary involved in the violation or could be applied to our entire enterprise in certain severe circumstances. Even a narrow scope suspension or debarment could result in negative publicity that could adversely affect our ability to renew contracts and to secure new contracts, both with the U.S. government and private customers, which could materially and adversely affect our business and results of operations. Fines and penalties could be imposed for failing to follow procurement integrity and bidding rules, employing improper billing practices, receiving or paying kickbacks, or filing false claims, among other potential violations. In addition, we could suffer serious reputational harm and the value of our common stock could be negatively affected if allegations of impropriety related to such contracts are made against us.

Risks Related to Our Intellectual Property

Litigation involving patents, patent applications and other proprietary rights is expensive and time-consuming. If we are involved in such litigation, it could interfere with our business.

Our success depends in part on not infringing patents and proprietary rights of third parties. The pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights.

In a patent infringement claim against us, we may assert, as a defense, that we do not infringe the relevant patent claims, that the patent is invalid or both. The strength of our defenses will depend on the patents asserted, the interpretation of these patents and/or our ability to invalidate the asserted patents. However, we could be unsuccessful in advancing non-infringement and/or invalidity arguments in our defense. In the United States, issued patents enjoy a presumption of validity, and the party challenging the validity of a patent claim must present clear and convincing evidence of invalidity, which is a high burden of proof. Conversely, the patent owner need only prove infringement by a preponderance of the evidence, which is a low burden of proof.

If we were found by a court to have infringed a valid patent, we could be prevented from using the patented technology or be required to pay the owner of the patent for the right to license the patented technology. If we decide to pursue a license to one or more of these patents, we may not be able to obtain a license on commercially reasonable terms, if at all, or the license we obtain may require us to pay substantial royalties or grant cross licenses to our patent rights. For example, if the relevant patent is owned by a competitor, that competitor may choose not to license patent rights to us. If we decide to develop alternative technology, we may not be able to do so in a timely or cost-effective manner, if at all.

In addition, because patent applications can take years to issue and are often afforded confidentiality for some period of time, there may currently be pending applications, unknown to us, that later result in issued patents that could cover one or more of our products.

It is possible that we may in the future receive, particularly as a public company, communications from competitors and other companies alleging that we may be infringing their patents, trade secrets or other intellectual property rights, offering licenses to such intellectual property or threatening litigation. In addition to patent infringement claims, third parties may assert copyright, trademark or other proprietary rights against us. We may need to expend considerable resources to counter such claims and may not be able to be successful in our defense. Our business may suffer if a finding of infringement is established.

Competitors can challenge the U.S. patents protecting our commercial partners' product candidates in connection with filing an ANDA for a generic version or a 505(b)(2) NDA for a modified version of our commercial partners' product candidates.

Separate and apart from the protection provided under the U.S. patent laws, drug candidates may be subject to the provisions of the Hatch-Waxman Act, which may provide drug candidates with either a three- or five-year period of marketing exclusivity following receipt of FDA approval. The Hatch-Waxman Act prohibits the FDA from accepting the filing of an ANDA application (for a generic product) or a 505(b)(2) NDA (for a modified version of the product) for three years for active drug ingredients previously approved by the FDA or for five years for active drug ingredients not previously approved by the FDA.

There is an exception, however, for newly approved molecules that allows competitors to challenge a patent beginning four years into the five-year exclusivity period by alleging that one or more of the patents listed in the FDA's list of approved drug products are invalid, unenforceable and/or not infringed and submitting an ANDA for a generic version of the innovator drug or a 505(b)(2) NDA for a modified version of the innovator drug. This patent challenge is commonly known as a Paragraph IV certification. Within the past several years, the generic industry has aggressively pursued approvals of generic versions of innovator drugs at the earliest possible point in time.

If a competitor is able to successfully obtain FDA approval for an ANDA or a 505(b)(2) NDA, the competitor may choose to launch its generic or modified version of the innovator drug. Any launch of a generic or modified version of our commercial partners' products will have a material adverse effect on demand for that product, our revenues and our results of operations.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We may rely on trade secrets to protect our proprietary know-how and technological advances, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain trade secret protection could enable competitors to use our proprietary information to develop products that compete with our products or cause additional, material adverse effects on our competitive business position.

Our ability to manufacture products for our commercial partners may be impaired if any of our manufacturing activities, or the activities of third parties involved in our manufacture and supply chain, are found to infringe patents of others.

Our ability to continue to manufacture products for our commercial partners, to utilize third parties to supply raw materials or other products, or to perform fill/finish services or other steps in our manufacture and supply chain, depends on our and their ability to operate without infringing the patents and other intellectual property rights of others. Other parties may allege that our manufacturing activities, or the activities of third parties involved in our manufacturing and supply chain, infringe patents or other intellectual property rights. A judicial decision in favor of one or more parties making such allegations could preclude the manufacture of the products to which those intellectual property rights apply, which could materially harm our business, operating results and financial condition.

We may not be able to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property. If we are unable to adequately enforce our intellectual property rights throughout the world, our business, financial condition, and results of operations could be adversely impacted.

Any trademarks we have obtained or may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our products that are approved for marketing from the products of our competitors. Once we select new trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our drugs, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

Risks Relating to Our Securities

The market price and trading volume of our common stock have been and may continue to be volatile, which could result in rapid and substantial losses for our shareholders.

The market price for our common stock has been volatile and may continue to fluctuate or may decline significantly in the future. An active, liquid and orderly market for our common stock may not be achieved and sustained, which could depress the trading price of our common stock or cause it to continue to be highly volatile or subject to wide fluctuations. Some of the factors that could negatively affect our share price or result in fluctuations in the price or trading volume of our common stock include, among other things:

- FDA, state or international regulatory actions, including actions on regulatory applications for any of our commercial partners' product candidates;
- noncompliance with applicable state, federal and international data privacy and security laws and regulations including, without limitation, the General Data Protection Regulations (Regulation (EU) 2016/679), as amended, and the California Consumer Privacy Act of 2018, as amended legislative or regulatory changes;
- judicial pronouncements interpreting laws and regulations;
- changes in government programs;

- announcements of new products, services or technologies, commercial relationships, acquisitions or other events by us or our competitors;
- changes in demand for or pricing of our customers' products;
- the sales ramp and trajectory for our formulation, development and manufacturing services;
- market conditions in the pharmaceutical and biotechnology sectors;
- fluctuations in stock market prices and trading volumes of similar companies;
- changes in accounting principles;
- litigation or public concern about the safety of our products or similar products;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant shareholders;
- our announcement of financing transactions, including debt, convertible notes, etc.; and
- actions by institutional or activist shareholders.

These broad market and industry factors may decrease the market price of our common stock, regardless of our actual operating performance. In addition, in the past, following periods of volatility in the overall market and decreases in the market price of a company's securities, securities class action litigation has often been instituted against these companies. Following the decrease in our trading price in May 2018, a securities class action lawsuit was filed against us which settled in 2022. Any other securities class actions that may be brought against us, could result in substantial costs and a diversion of our management's attention and resources.

We have never paid cash dividends on our common stock and do not intend to do so for the foreseeable future, which may make our stock less attractive.

We have never paid cash dividends on our common stock and we do not anticipate that we will pay any cash dividends on our common stock for the foreseeable future. Additionally, our ability to pay cash dividends is currently prohibited by the terms of our credit facility with Royal Bank of Canada. Accordingly, any return on an investment in our common stock will be realized, if at all, only when shareholders sell their shares. In addition, our failure to pay cash dividends may make our stock less attractive to investors, adversely impacting trading volume and price.

Some provisions of our charter documents and Pennsylvania law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our shareholders, and may prevent attempts by our shareholders to replace or remove our current management.

Provisions in our articles of incorporation and amended and restated bylaws could make it more difficult for a third-party to acquire us or increase the cost of acquiring us, even if doing so would benefit our shareholders, or remove our current management. These include provisions that:

- divide our board of directors into three classes with staggered three-year terms;
- provide that a special meeting of shareholders may be called only by a majority of our board of directors;
- establish advance notice procedures with respect to shareholder proposals to be brought before a shareholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of director;
- provide that shareholders may only act at a duly organized meeting; and
- provide that members of our board of directors may be removed from office by our shareholders only for cause by the affirmative vote of 75% of the total voting power of all shares entitled to vote generally in the election of directors.

These provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it more difficult for shareholders to replace members of our board of directors, who are responsible for appointing the members of our management. Because we are incorporated in Pennsylvania, we are governed by the provisions of the Pennsylvania Business Corporation Law of 1988, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our shareholders. Under Pennsylvania law, a corporation may not, in general, engage in a business combination with any holder of 20% or more of its capital stock unless the holder has held the stock for five years or, among other things, the board of directors has approved the transaction. Any provision of our articles of incorporation or bylaws or Pennsylvania law that has the effect of delaying or deterring a change in control could limit the opportunity for our shareholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

We have a limited number of authorized shares of common stock available for issuance and will need to seek shareholder approval to amend our Second Amended and Restated Articles of Incorporation to effect an increase in the number of authorized shares of our common stock.

Our Second Amended and Restated Articles of Incorporation currently authorizes us to issue up to 95,000,000 shares of common stock. As of December 31, 2022, following our concurrent offerings of common stock and Series A Convertible Preferred Stock, or Series A preferred stock, in December 2022, we had only 10,411,132 authorized but unissued shares of our common stock, of which 9,272,678 are currently reserved for issuance of outstanding options, restricted stock units, and warrants. We currently do not have a sufficient number of authorized and unreserved shares of common stock to permit the conversion of the Series A preferred stock.

The Series A preferred stock is only convertible into common stock upon receipt of shareholder approval of an increase in the number of authorized shares of our common stock. Pursuant to the certificate of designation of preferences, rights and limitations of the Series A preferred stock, or the Certificate of Designations, we have agreed to seek shareholder approval of an amendment to our Second Amended and Restated Articles of Incorporation to effect an increase in the number of authorized shares of common stock in an amount sufficient to permit the conversion in full of the Series A preferred stock. If such shareholder approval is not obtained by June 30, 2023, the then-in-effect conversion rate of the Series A preferred stock shall be increased by 10% and will increase by an additional 10% per year on June 30 of each year for which shareholder approval has not yet been obtained, subject to certain limits. We can offer no assurance that we will be able to obtain such approval by June 2023 or at all.

Furthermore, an increase in the authorized number of shares of common stock and the subsequent issuance of such shares could have the effect of delaying or preventing a change in control of our company without further action by our shareholders. Shares of authorized and unissued common stock could, within the limits imposed by applicable law, be issued in one or more transactions which would make a change in control of our company more difficult, and therefore less likely.

General Risk Factors

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities.

If securities or industry analysts do not continue to publish research or reports, or if they publish unfavorable research or reports, about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. We currently have limited research coverage by securities and industry analysts. If additional securities or industry analysts do not commence coverage of our company, the trading price for our stock could be negatively impacted. In the event we obtain securities or industry analyst coverage, if one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors' views of us.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that will need to be frequently evaluated. Section 404 of the Sarbanes-Oxley Act requires public companies to conduct an annual review and evaluation of their internal controls and attestations of the effectiveness of internal controls by independent auditors (as a smaller reporting company, the latter requirement does not apply to us). Our failure to maintain the effectiveness of our internal controls in accordance with the requirements of the Sarbanes-Oxley Act could have a material adverse effect on our business. We could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on the price of our common stock.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal executive offices are located at 1 E. Uwchlan Ave, Suite 112, Exton, Pennsylvania 19341. We also lease and operate:

- a 97,000 square foot, DEA-licensed facility in Gainesville, Georgia, pursuant to a lease which expires in December 2042;
- a 24,000 square foot development and high-potency product services facility in Gainesville, GA, pursuant to a lease which expires in June 2025; and
- a 24,500 square foot development facility focused on advanced dosage forms in San Diego, California, pursuant to a lease which expires in January 2031.

Item 3. Legal Proceedings

Information regarding legal and regulatory proceedings is set forth in note 7 to our consolidated financial statements beginning on page F-1 of this Annual Report on Form 10-K, and is incorporated by reference herein. We are also engaged in various other legal actions arising in the ordinary course of our business (such as, for example, proceedings relating to employment matters or the initiation or defense of proceedings relating to intellectual property rights) and, while there can be no assurance, we believe that the ultimate outcome of these other legal actions will not have a material adverse effect on our business, results of operations, financial condition or cash flows.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock is traded on the Nasdaq Capital Market under the symbol "SCTL."

Holders of Common Stock

As of February 22, 2023, there were 6 holders of record of our common stock. The actual number of holders of our common stock is greater than this number of record holders, and includes shareholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees. This number of holders of record also does not include shareholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any cash dividends on our common stock and our ability to pay cash dividends is currently prohibited by the terms of our credit facility with Royal Bank of Canada. We do not anticipate paying cash dividends on our common stock in the foreseeable future. Payment of future dividends, if any, on our common stock will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, anticipated cash needs and plans for expansion.

Recent Sales of Unregistered Offerings

None.

Issuer Repurchases of Equity Securities

None.

Securities Authorized for Issuance Under Equity Compensation Plans

Other information about our equity compensation plans is incorporated herein by reference to Part III, Item 12 of this Annual Report on Form 10-K.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes appearing elsewhere. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions and other factors that could cause actual results to differ materially from those made, projected or implied in the forward-looking statements. Our actual results may differ materially from those discussed below. Please see "Forward-Looking Statements" and "Risk Factors" included in Part I, Item 1A of this Annual Report on Form 10-K for factors that could cause or contribute to such differences.

Overview

We are a bi-coastal contract development and manufacturing organization, or CDMO, with capabilities spanning pre-investigational new drug development to commercial manufacturing and packaging for a wide range of therapeutic dosage forms with a primary focus on small molecules. With an expertise in solving complex manufacturing problems, Societal is a leading CDMO providing development, end-to-end regulatory support, clinical and commercial manufacturing, aseptic fill/finish, lyophilization, packaging and logistics services to the global pharmaceutical market. In addition to our experience in handling DEA-controlled substances and developing and manufacturing modified-release dosage forms, Societal has the expertise to deliver on our clients' pharmaceutical development and manufacturing projects, regardless of complexity level. We do all of this in our state-of-the-art facilities that, in the aggregate, total 145,000 square feet, in Gainesville, Georgia and San Diego, California.

We currently manufacture the following key products with our key commercial partners: Ritalin LA®, Focalin XR®, Verelan PM®, Verelan SR®, Verapamil PM, Verapamil SR and Donnatal liquids and tablets. We also support numerous development stage products.

During the third quarter of 2021, we acquired IriSys, LLC, or IriSys, an independent San Diego-based CDMO. The acquisition provided us significant new capabilities beyond oral solid dose, including sterile and non-sterile injectables, liquid and powder filled capsules, tablets, oral liquids, liposomes and nano/micro-particles and topical formulations.

Our manufacturing and development capabilities include product development from formulation through clinical trial and commercial manufacturing, and specialized capabilities for solid oral dosage forms, with specialization in modified release technologies and facilities to handle high potent compounds and controlled substances, liposomes and nano/microparticles, topicals and oral liquids. In September 2022, Societal announced a new state of the art, aseptic fill/finish and lyophilization suite in our San Diego facility to further our goal of offering end-to-end solutions to our clients. In addition to providing manufacturing capabilities, we offer our customers clinical trial support including over-encapsulation, comparator sourcing, packaging, labeling, storage and distribution. We have a bi-coastal footprint from which to better serve clients within the U.S., as well as globally. In a typical collaboration between us and our commercial partners, we continue to work with our partners to develop product candidates or new formulations of existing product candidates. We also typically exclusively manufacture and supply clinical and commercial supplies of these proprietary products and product candidates.

We use cash flow generated by our business primarily to fund the growth of our CDMO business and to make payments under our credit facility. We believe our business will continue to contribute cash to fund our growth, make payments under our credit facility and other general corporate purposes.

Global economic and supply conditions

Global economic conditions, logistics and supply chain issues continue to present obstacles to our business, including challenges related to the COVID-19 pandemic.

We rely on third-party manufacturers to supply our manufacturing components, supplies and related materials, which in some instances are supplied from a single source. Prolonged disruptions in the supply of any of our third-party materials, difficulty implementing new sources of supply or significant price increases could have an adverse effect on our results. While the impact of COVID-19 has lessened in many ways, we are experiencing a higher level of residual supply chain disruptions that we are actively managing to meet our production timelines and that may constrain our ability to capture additional growth opportunities, beyond our established projections, from customers who would otherwise want to increase their safety stock of the products that we produce.

We also continue to closely monitor economic developments related to COVID-19 and other diseases and geopolitical conflicts, such as the conflict between Russia and Ukraine, which continue to have adverse effects on the U.S. and global markets.

We continue to anticipate a general slowdown in clinical development activity as a result of clinical failures and/or a lack of adequate funding to go forward. We are making efforts to adapt to these market changes, including a reconfiguration of our business development team to be better positioned in the longer-term by focusing on account management roles and replacing lost positions in strategic focus areas. The anticipated slowdown and/or the reconfiguration may cause a reduction in the number of business development opportunities that we will be able to pursue in 2023. We also expect to face continuing inflationary pressures on raw materials, labor and logistics during 2023. Finally, we were impacted by higher variable base interest rates on our borrowings under credit agreements during the second half of 2022, and while we believe that we have been able to capture overall interest savings as a result of the December 2022 refinancing, we expect those improvements could be partially offset by variable base interest rate increases in 2023.

Financial overview

Revenues

We recognize three types of revenue: manufacturing, profit-sharing and research and development.

Manufacturing

We recognize manufacturing revenue from the sale of products we manufacture for our commercial partners. Manufacturing revenues are recognized upon transfer of control of a product to a customer, generally upon shipment, based on a transaction price that reflects the consideration we expect to be entitled to as specified in the agreement with the commercial partner, which could include pricing and volume-based adjustments.

Profit-sharing

In addition to manufacturing revenue, certain customers who use our technologies are subject to agreements that provide us intellectual property sales-based profit-sharing and/or royalties consideration, collectively referred to as profit-sharing, computed on the net product sales of the commercial partner. Profit-sharing revenues are generally recognized under the terms of the applicable license, development and/or supply agreement. We have determined that in our arrangements, the license for intellectual property is not the predominant item to which the profit-sharing relates, so we recognize revenue upon transfer of control of the manufactured product. In these cases, significant judgment is required to calculate the estimated variable consideration from such profit-sharing using the expected value method based on historical commercial partner pricing and deductions. Estimated variable consideration is partially constrained due to the uncertainty of price adjustments made by our commercial partners, which are outside of our control. Factors causing price adjustments by our commercial partners include increased competition in the products' markets, mix of volume between the commercial partners' customers, and changes in government pricing.

Research and development

Research and development revenue includes services associated with formulation, process development, clinical trials materials services, as well as custom development of manufacturing processes and analytical methods for a customer's non-clinical, clinical and commercial products. Such revenues are recognized at a point in time or over time depending on the nature and particular facts and circumstances associated with the contract terms.

In contracts that specify milestones, we evaluate whether the milestones are considered probable of being achieved and estimate the amount to be included in the transaction price using the most likely amount method. Milestone payments related to arrangements under which we have continuing performance obligations are deferred and recognized over the period of performance. Milestone payments that are not within our control, such as submission for approval to regulators by a commercial partner or approvals from regulators, are not considered probable of being achieved until those submissions are submitted by the customer or approvals are received.

In contracts that require revenue recognition over time, we utilize input or output methods, depending on the specifics of the contract, that compare the cumulative work-in-process to date to the most current estimates for the entire performance obligation. Under these contracts, the customer typically owns the product details and process, which have no alternative use. These projects are customized to each customer to meet its specifications, and typically only one performance obligation is included. Each project represents a distinct service that is sold separately and has stand-alone value to the customer. The customer also retains control of its product as the product is being created or enhanced by our services and can make changes to its process or specifications upon request.

Cost of sales and selling, general and administrative expenses

Cost of sales consists of inventory costs, including production wages, material costs and overhead, and other costs related to the recognition of revenue. Selling, general and administrative expenses consists of salaries and related costs for administrative, public company costs, business development personnel as well as legal, patent-related expenses and consulting fees. Public company costs include compliance, auditing services, tax services, insurance and investor relations.

In October 2021, we integrated and reorganized our collective employee base to support a multi-site organization. As a result, certain employees in administrative roles are supporting the entire company instead of plant operations. Costs associated with these employees, including employee compensation and other expenses, are classified in selling, general and administrative expenses prospectively from October 1, 2021.

For the year ended December 31, 2021, we qualified for approximately $4.4 million of federal employee retention credits, all of which was recognized as an offset to expense. We did not recognize any additional credits during the year ended December 31, 2022, and do not anticipate any additional credits in future periods.

Amortization of intangible assets

Historically, we recognized amortization expense related to an intangible asset for our profit-sharing and contract manufacturing relationships on a straight-line basis over an estimated useful life of six years. Amortization stopped when the intangible asset reached the end of its useful life in April 2021. With the acquisition of IriSys, we are recognizing amortization expense related to acquired customer relationships, backlog and trademarks and trade names on a straight-line basis over estimated useful lives of 7.0, 2.4, and 1.5 years, respectively.

Interest expense

Interest expense for the periods presented primarily relates to the $100.0 million senior secured term loans with Athyrium Opportunities III Acquisition LP and the amortization of related financing costs, as well as other smaller instruments.

In December 2022, we completed a refinancing that included the repayment of $100.0 million of outstanding term loans with Athyrium funded in part by $36.9 million of new term loan borrowings with Royal Bank of Canada and $39.0 million of gross proceeds from the sale and leaseback of our commercial manufacturing campus in Gainesville, Georgia. We expect that future periods will include a lower amount of aggregate interest expense related to these transactions and the amortization of related financing costs due to lower amount of aggregate principal and lower variable interest margins as compared to the Athyrium borrowings.

Net operating losses and tax carryforwards

As of December 31, 2022, we had federal net operating loss, or NOL, carry forwards of approximately $125.6 million, substantially all of which have an indefinite carry forward period. We also had $135.4 million of state NOL carry forwards available to offset future taxable income that will begin to expire at various dates beginning in 2028 if not utilized. We believe that it is more likely than not that our deferred income tax assets will not be realized, and as such, there is a full valuation allowance.

Key indicators of performance

To evaluate our performance, we monitor a number of industry-standard key indicators such as:

- *Safety and human capital management*, as measured by recordable injuries, good saves and employee retention;
- *Operational excellence*, as measured by the percentage of our orders that are delivered on-time and in full;
- *New business growth*, as measured by value of new contracts signed; and
- *Financial operating results*, as measured by revenue and EBITDA, as adjusted.

EBITDA, as adjusted, is a non-GAAP measure that we discuss and reconcile to its nearest GAAP measure elsewhere in our public financial reporting. We believe that supplementing our financial results presented in accordance with GAAP with non-GAAP measures is useful to investors, creditors and others in assessing our performance. These measurements should not be considered in isolation or as a substitute for reported GAAP results because they may include or exclude certain items as compared to similar GAAP-based measurements, and such measurements may not be comparable to similarly-titled measurements reported by other companies. Rather, these measurements should be considered as an additional way of viewing aspects of our operations and gaining an understanding of our business.

Results of operations

Comparison of years ended December 31, 2022 and 2021

(in millions)	Year ended December 31, 2022	2021
Revenue	$ 90.2	$ 75.4
Operating expenses:		
Cost of sales (excluding amortization of intangible assets)	67.1	55.6
Selling, general and administrative	21.9	18.4
Amortization of intangible assets	0.9	1.0
Total operating expenses	89.9	75.0
Operating income	0.3	0.4
Interest expense	(14.1)	(15.1)
(Loss) gain on extinguishment of debt	(5.0)	3.3
Loss before income taxes	(18.8)	(11.4)
Income tax expense	1.1	—
Net loss	$ (19.9)	$ (11.4)

Revenue. The increase of $14.8 million was primarily driven by an increase in European Ritalin LA demand from our new customer InfectoPharm, as well as an increase in revenue from our largest commercial customer Teva, correlated with pull through in demand resulting from market share gains against the sole competitor for the Verapamil SR products. In addition, there were higher revenues from our clinical trial materials business as well as a full year of revenue resulting from the acquisition of IriSys compared to approximately five months of revenue in 2021. The increase in revenue was partially offset by a decline in revenue from Lannett's commercial sales of the Verapamil PM products.

Cost of sales. The increase of $11.5 million was primarily due to the acquisition of the San Diego facility and certain 2021 employment incentive tax credits that were not repeated in 2022 resulting in increased expense in 2022. These increases were partially offset by the reallocation of expenses reflecting the post-acquisition organizational structure.

Selling, general and administrative. The increase of $3.5 million was primarily related to costs associated with the debt refinancing in the fourth quarter of 2022 and increased personnel costs tied to the reallocation of expenses. Specifically, effective October 1, 2021, certain employees who previously supported the our plant operations now support our multi-site organization structure and operations. Accordingly, expenses associated with these employees have been reclassified from cost of sales to selling, general and administrative expenses. These increases were offset by lower IriSys acquisition and integration costs.

Amortization of intangible assets. The decrease of $0.1 million was primarily the result of amortizing a lower amount of IriSys intangible assets in 2022 as compared to a higher amount of historical intangible assets in the first part of 2021, partially offset by an approximately four-month period in 2021 prior to the IriSys acquisition when no intangible assets were being amortized.

Interest expense. The decrease of $1.0 million was primarily due to the extension of the maturity date of our prior term loans, which deferred a portion of the interest expense from non-cash amortization of financing expenses until they were written off as loss on extinguishment of debt in December 2022 (see below), as well as increased capitalized interest. These decreases were partially offset by a full period of interest on the debt portion of the IriSys acquisition purchase price and an increase in the variable LIBOR component of interest on prior term loans with Athyrium.

Loss or gain on extinguishment of debt. In December 2022, as a result of fully paying off our loan with Athyrium, we recorded a loss on extinguishment of debt for the write-off of certain deferred financing costs. In June 2021, we received forgiveness of principal and interest on a note issued under a Federal COVID-19 relief program and recorded a gain on extinguishment of debt.

Comparison of years ended December 31, 2021 and 2020

(in millions)	Year ended December 31, 2021	2020
Revenue	$ 75.4	$ 66.5
Operating expenses:		
Cost of sales (excluding amortization of intangible assets)	55.6	54.1
Selling, general and administrative	18.4	18.1
Amortization of intangible assets	1.0	2.6
Total operating expenses	75.0	74.8
Operating loss	0.4	(8.3)
Interest expense	(15.1)	(19.2)
Gain on extinguishment of debt	3.3	—
Net loss	$ (11.4)	$ (27.5)

Revenue. The increase of $8.9 million was primarily the result of increases in revenue due to the acquisition of IriSys as well as higher revenues from our clinical trial materials business including revenue from a commercial product tech transfer project. Despite the discontinuation of two commercial product lines by our commercial partners announced in the first quarter of 2020, our legacy commercial business has remained relatively flat in 2021 compared to 2020 as our other commercial products saw growth in 2021 compared to 2020 rebounding from lower volumes in 2020 due to impacts to the market from COVID-19.

Cost of sales. The increase of $1.5 million was primarily due to costs from the San Diego facility due to the acquisition of IriSys and is partially offset by lower costs due to the prior year reduction in force and certain employment incentive tax credits in 2021.

Selling, general and administrative. The increase of $0.3 million was primarily related to deal and integration costs related to the acquisition of IriSys and administrative expenses associated with the addition of our San Diego team offset by lower public company costs and stock-based compensation expense. Specifically, effective October 1, 2021, certain employees who previously supported our plant operations now support our multi-site organization structure and operations. Accordingly, expenses associated with these employees have been reclassified from cost of sales to selling, general and administrative expenses.

Amortization of intangible assets. The decrease of $1.6 million was the result of amortizing a lower amount of IriSys intangible assets in 2021, as compared to a higher amount of historical intangible assets in 2020 and the first part of 2021, as well as an approximately four-month period in 2021 prior to the IriSys acquisition when no intangible assets were being amortized.

Interest expense. The decrease of $4.1 million was primarily due to reduced term loan borrowings under the Athyrium Credit Agreement as well as a decrease in the LIBOR base rate of interest on our term loans under the Athyrium Credit Agreement. This decrease was partially offset by an increase in interest from the sellers note which was a component of the IriSys acquisition purchase price.

Gain on extinguishment of debt. In June 2021, we received forgiveness of principal and interest on a note issued under a Federal COVID-19 relief program and recorded a gain on extinguishment of debt.

Liquidity and capital resources

At December 31, 2022, we had $15.0 million in cash and cash equivalents.

Since our inception, we have financed our operations and capital expenditures primarily from results of operations, the issuance of equity and debt, and recently to a lesser extent real estate transactions. During the year ended December 31, 2022, our capital expenditures were $8.4 million to scale and support our expansion of capabilities.

In December 2022, we completed a refinancing that included the repayment of $100.0 million of outstanding term loans with Athyrium, funded by entering into three transactions: (i) we raised gross proceeds of $39.0 million through the sale and subsequent leaseback of our commercial manufacturing campus located in Gainesville, Georgia (see below); (ii) we raised net proceeds of $32.9 million from the issuance of common and preferred stock; and (iii) we borrowed $36.9 million under a new term loan with Royal Bank of Canada. Among other things, the refinancing has resulted in a reduction to our leverage ratio, a reset of our financial covenants and a reduction in the amount of cash payable for interest in future periods.

We are currently party to a credit agreement with Royal Bank of Canada, or the Credit Agreement, for a term loan with a principal amount of $36.9 million. The outstanding principal amount will be repaid in equal quarterly payments totaling $1.8 million in 2023, $2.8 million 2024 and $3.7 million in 2025, with the remaining principal balance due December 16, 2025. If the Company completes a sale of certain real property by December 14, 2023 and makes the $10.0 million principal repayment disclosed below, the quarterly principal payments will be reduced proportionately to the reduction in principal.

Subject to certain exceptions, we are required to make mandatory prepayments with the cash proceeds received in respect of asset sales, extraordinary receipts and debt issuances, upon a change of control and specified other events. Additionally, we are obligated to repay $10.0 million of principal by December 14, 2023 upon the sale of certain real property adjacent to its Gainesville, Georgia manufacturing campus. If that property is not sold by December 14, 2023, we will be required to pay a fee of $0.4 million and increase each of our quarterly principal payments by $0.2 million until that property is sold and the $10,000 principal payment is made.

The Credit Agreement also includes certain financial covenants that the Company will need to satisfy on a quarterly basis, including: (i) maintaining a net leverage ratio less than 3.75:1.00, stepping down to 2.75:1.00 over time; (ii) maintaining a fixed charge coverage ratio greater than 1.15:1.00; and (iii) maintaining no less than $4.0 million cash and cash equivalents on hand, stepping up to $5.0 million over time.

In September 2022, we signed a sales and purchase agreement to sell approximately 121 acres of land adjacent to our Gainesville, Georgia manufacturing campus for expected proceeds of $9.1 million, which we are obligated to use to repay outstanding balances on the Credit Agreement. The land sale is expected to close in the second half of 2023. Until closing, the sale of the land is subject to customary closing conditions for transactions of this type, including completion of title and environmental due diligence and receipt of certain zoning approvals and permits.

In August 2021, we acquired IriSys for $50.2 million by paying $24.0 million in cash, net of cash acquired, and issuing a note and equity with fair values of $5.3 million and $20.9 million, respectively, to the former equity holders of IriSys.

We may require additional financing or choose to refinance certain of these instruments, which could include strategic development, licensing activities and/or marketing arrangements, public or private sales of equity or debt securities or debt refinancing. Financing may not be available on acceptable terms, or at all, and our failure to raise capital when needed could materially adversely impact our growth plans and our financial condition or results of operations. If and until we are able to obtain shareholder approval to increase the number of shares of common stock authorized under our articles of incorporation, we will be limited in the number of additional shares we will be able to issue in future periods. Further, our ability to access capital market or otherwise raise capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, financial markets in the United States and worldwide resulting from COVID-19 and other diseases and geopolitical conflicts. Additional debt or equity financing, if available, may be dilutive to the holders of our common stock, may involve significant cash payment obligations and covenants that restrict our ability to operate our business or to access capital, and may further restrict dividend payments.

Sources and uses of cash

	Year ended December 31,		
(amounts in millions)	**2022**	**2021**	**2020**
Net cash (used in) provided by:			
Operating activities	$ (3.6)	$ 10.9	$ 9.2
Investing activities	(8.4)	(29.3)	(7.6)
Financing activities	1.8	19.9	4.1
Total	$ (10.2)	$ 1.5	$ 5.7

Cash flows from operating activities represents our net loss as adjusted for stock-based compensation expense, non-cash interest expense, depreciation expense, impairment expense, amortization of intangible assets, deferred income tax expense and gains and losses on extinguishment of debt as well as changes in operating assets and liabilities. The $14.5 million decrease in cash flows from operations in 2022 compared to 2021 was primarily due changes in operating assets and liabilities, including a $4.8 million effect from changes in accrued interest due to the timing of the fourth quarter 2021 interest payment on the prior Athyrium credit agreement that was not paid until 2022. Additionally, we experienced changes to inventory, accrued expenses and accounts receivable collectively resulting in a $10.0 million decrease in cash flows, primarily caused by accrued costs related to the December 2022 debt refinancing that will be paid in 2023, growth in our development business and changes to customer ordering patterns. The increase in cash flows from operations in 2021 compared to 2020 was primarily due to the decrease in net loss, net of various non-cash items described above, an increase in accrued interest for the same reasons described above, and an increase in accrued expenses, partially offset by increases in accounts receivable and contract assets.

Net cash used in investing activities for each of the three years includes capital expenditures to scale and support our expansion of capabilities. In 2021, net cash used in investing activities also included $24.0 million paid to acquire IriSys.

Net cash provided by financing activities included:

- During 2022, net proceeds from the issuance of preferred and common stock of $33.0 million, $36.9 million from the term loan with Royal Bank of Canada, and $37.3 from the sale-leaseback of our commercial manufacturing campus in Gainesville, Georgia, partially offset by debt repayments of $103.0 million, financing costs of $2.2 million, and $0.2 million to pay employee tax withholdings upon vesting of equity awards.

- During 2021, net proceeds from an issuance of common stock of $32.1 million, partially offset by debt repayments of $10.1 million, financing costs of $1.4 million paid in connection with the debt amendments and common stock issuances, and $0.7 million to pay employee tax withholdings upon vesting of equity awards.

- During 2020, net proceeds of $11.1 million from issuance of common stock in an at-the-market offering and $4.4 million from a note issued under a Federal COVID-19 relief program, partially offset by a $1.1 million repayment of the note, $10.1 million to repay term loans with Athyrium and $1.1 million to pay employee tax withholdings upon vesting of equity awards.

Forward-looking factors

Our future use of operating cash and capital requirements will depend on many forward-looking factors, including the following:

- the extent to which we in-license, acquire or invest in products, businesses and technologies;

- the timing and extent of our manufacturing and capital expenditures;

- our ability to maintain or expand our relationships and contracts with our commercial partners;

- our ability to grow and diversify our business with new customers, including our ability to meet desired project outcomes with development customers;

- our ability to regain profitability;

- our ability to comply with stringent U.S. & foreign government regulation in the manufacture of pharmaceutical products, including cGMP and DEA requirements;

- our ability to raise additional funds through equity or debt financings or sale of real-estate or other assets;

- the costs of maintaining, enforcing and defending intellectual property claims;

- the extent to which health epidemics and other outbreaks of communicable diseases, including the COVID-19 pandemic, could disrupt our operations or materially and adversely affect our business and financial conditions; and

- the extent to which inflation, global instability, including political instability and any resulting sanctions, export controls or other restrictive actions that may be imposed by the U.S. and/or other countries against governmental

or other entities may disrupt our business operations or financial condition or the financial condition of our customers and suppliers.

We might use existing cash and cash equivalents on hand, additional debt, equity financing, sale of real-estate or other assets or out-licensing revenue or a combination thereof to fund our operations or acquisitions. If we increase our debt levels, we might be restricted in our ability to raise additional capital and might be subject to financial and restrictive covenants. If and until we are able to obtain shareholder approval to increase the number of shares of common stock authorized under our articles of incorporation, we will be limited in the number of additional shares we will be able to issue in future periods. If we do issue additional equity in future periods, our shareholders may experience dilution. This dilution may be significant depending upon the amount of equity or debt securities that we issue and the prices at which we issue any securities.

Contractual commitments

The table below reflects our contractual commitments as of December 31, 2022:

	Payments due by period				
(in millions)	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Debt obligations (1):					
Principal	$ 41.3	$ 7.6	$ 33.4	$ 0.1	$ 0.2
Interest	9.9	3.5	6.3	0.1	—
Purchase obligations (2)	9.7	9.2	0.5	—	—
Operating leases (3)	9.4	1.2	2.4	2.2	3.6
Other long-term liabilities (4)(5)	94.5	3.5	7.4	7.8	75.8
Total	$ 164.8	$ 25.0	$ 50.0	$ 10.2	$ 79.6

(1) Debt obligations consist of principal and interest on $36.9 million of an outstanding term loan under our credit facility with Royal Bank of Canada, $4.1 million of notes issued to the former members of IriSys and a small finance lease. Because the Royal Bank of Canada term loan bears interest at a variable rate based on SOFR, we estimated future interest commitments utilizing the SOFR rate as of December 31, 2022. In accordance with U.S. GAAP, the future interest obligations are not recorded on our consolidated balance sheet.

(2) Purchase obligations consist of cancelable and non-cancelable purchase commitments related to inventory, capital expenditures and other goods or services. In accordance with U.S. GAAP, these obligations are not recorded on our consolidated balance sheets.

(3) We are party to two operating leases for development facilities in California and Georgia that end in 2031 and 2025, respectively. The leases each include options to extend at our discretion.

(4) We are party to a lease for a DEA-licensed facility in Georgia that ends in 2042. The lease includes the option to extend at our discretion. The principal component of this obligation is classified as a liability under U.S. GAAP, therefore we did not present it as an operating or capital lease in the table.

(5) We have entered into employment agreements with each of our named executive officers that provide for, among other things, severance commitments of up to $1.3 million should we terminate the named executive officers for convenience or if certain events occur following a change in control. In addition, we would be subject to other contingencies of up to $3.8 million in the aggregate if certain events occur following a change in control. Because these obligations are contingent, the amounts are not included in the table above.

Critical accounting policies and estimates

This management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We have determined that certain accounting policies and estimates are critical to the preparation of the financial statements. We have prepared the following additional disclosures to supplement our summary of significant accounting policies located in note 2 to the consolidated financial statements beginning on page F-1 of this Annual Report on Form 10-K.

Business combinations

Business acquisitions are accounted for in accordance with Accounting Standards Codification, or ASC, Topic 805, *Business Combinations*. In purchase accounting, identifiable assets acquired and liabilities assumed, are recognized at their estimated fair values at the acquisition date, and any remaining purchase price is recorded as goodwill. In determining the fair values of the consideration transferred, the assets acquired and the liabilities assumed, we make significant estimates and assumptions, particularly with respect to long-lived tangible and intangible assets. Critical estimates used in valuing tangible and intangible assets include, but are not limited to, future expected cash flows, discount rates, market prices and asset lives.

While we use our best estimates and assumptions as part of the purchase price allocation process to accurately value assets acquired and liabilities assumed at the business acquisition date, our estimates and assumptions are inherently uncertain and subject to refinement. As a result, during the purchase price allocation period, which is generally one year from the business acquisition date, we record adjustments to the assets acquired and liabilities assumed, with the corresponding offset to goodwill. For changes in the valuation of intangible assets between preliminary and final purchase price allocation, the related amortization is adjusted in the period it occurs. Subsequent to the purchase price allocation period any adjustment to assets acquired or liabilities assumed is included in operating results in the period in which the adjustment is determined.

Although our estimates of fair value are based upon assumptions believed to be reasonable, actual results may differ. See note 15 to the consolidated financial statements beginning on page F-1 of this report for more information related to the acquisition of IriSys.

Revenue recognition for variable consideration in sales-based profit-sharing arrangements

For sales-based profit-sharing where the license for intellectual property is not deemed to be the predominant item to which the profit-sharing relates, we recognize revenue upon transfer of control of the manufactured product. In these cases, significant judgment is required to calculate the estimated variable consideration from such profit-sharing using the expected value method based on historical commercial partner pricing and deductions.

We are required to exercise significant judgment to estimate the value of the variable consideration, which we partially constrain due to the uncertainty of price adjustments made by our commercial partners, which are outside of our control. Factors causing price adjustments by our commercial partners include increased competition in the products' markets, mix of volume between the commercial partners' customers, and changes in government pricing. If we were to increase or decrease the percentage value of the constraint by 5%, we would recognize a corresponding decrease or increase, respectively, to revenue and earnings of $0.5 million.

Impairment of goodwill

We are required to review, on an annual basis, the carrying value of goodwill to determine whether impairment may exist. The impairment analysis for goodwill consists of an optional qualitative assessment potentially followed by a quantitative analysis. If we determine that the carrying value of our reporting unit exceeds its fair value, an impairment charge to goodwill is recorded for the excess.

The critical judgments involved in our annual qualitative test include an assessment of unfavorable events and a judgment whether those events put our goodwill at risk of impairment, which if determined to be at risk would require us to perform a quantitative test. The critical judgments and estimates in our quantitative test include selection and weighting of available valuation methods and the selection of assumptions that may be used in those methods.

In 2022, we concluded qualitatively that our goodwill was not at risk of impairment due to the substantial excess of fair value over the carrying value of our reporting unit that we observed in prior period quantitative testing. The carrying value of our goodwill was $41.1 million at December 31, 2022. Any changes to our judgments or estimates could result in a goodwill impairment of up to that amount in a future period.

Item 7A. Quantitative and qualitative disclosures about market risk

We are exposed to market risks in the ordinary course of our business. These market risks are principally limited to interest rate fluctuations. At December 31, 2022, we had approximately $6.0 million invested in money market instruments. We believe our policy of investing in highly-rated securities, whose liquidities are, at December 31, 2022, all less than two months, minimizes such risks. Due to the short-term duration of our investment portfolio and the low-risk profile of our investments, an immediate increase in interest rates would not have a material effect on the fair market value of our portfolio. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our investment portfolio. We do not enter into investments for trading or speculative purposes. Our Royal Bank of Canada term loan interest expense is currently based on the current committed rate of three-month forward SOFR plus 4.5%. An increase in SOFR of 1% would result in additional interest expense of $0.4 million annually.

Item 8. Financial Statements and Supplementary Data

Our consolidated financial statements and the report of our independent registered public accounting firm are included at the end of this Annual Report on Form 10-K beginning on page F-1.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosures

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures, as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of December 31, 2022. We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure.

A control system, no matter how well conceived and operated, can provide only reasonable, and not absolute, assurance that the objectives of the control system will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. However, our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives. Based on the evaluation of our disclosure controls and procedures as of December 31, 2022, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance of the reliability of financial reporting and of the preparation of financial statements for external reporting purposes, in accordance with U.S. generally accepted accounting principles.

Internal control over financial reporting includes policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and disposition of assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with the authorization of its management and directors; and (3) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on its financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of the effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies and procedures included in such controls may deteriorate.

Our management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2022. In making this assessment, management used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control – Integrated Framework (2013). These criteria are in the areas of control environment, risk assessment, control activities, information and communication, and monitoring. Management's assessment included extensive documentation, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting.

Based on management's processes and assessment, as described above, management has concluded that, as of December 31, 2022, our internal control over financial reporting was effective.

Item 9B. Other Information

None

Item 9C. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections

Not applicable

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information with respect to this item will be set forth in the Proxy Statement for the 2023 Annual Meeting of Shareholders, or the Proxy Statement, under the headings "Board of Directors," "Executive Officers," "Section 16(a) Beneficial Ownership Reporting Compliance," and "Corporate Governance and Risk Management" and is incorporated herein by reference. The Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 11. Executive Compensation

Information with respect to this item will be set forth in the Proxy Statement under the headings "Director Compensation," "Executive Compensation," and "Corporate Governance and Risk Management" is incorporated herein by reference. The Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters

Information with respect to this item will be set forth in the Proxy Statement under the headings "Security Ownership of Directors, Certain Beneficial Owners and Management," "Executive Compensation," and "Director Compensation," and is incorporated herein by reference. The Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Information with respect to this item will be set forth in the Proxy Statement under the headings "Certain Relationships and Related Party Transactions" and "Corporate Governance and Risk Management" and is incorporated herein by reference. The Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 14. Principal Accounting Fees and Services

Information with respect to this item will be set forth in the Proxy Statement under the heading "Independent Registered Public Accounting Firm," and is incorporated herein by reference. The Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

PART IV

Item 15. Exhibits, Consolidated Financial Statement Schedules

(a)(1) Consolidated Financial Statements.

The following consolidated financial statements are filed as a part of this Annual Report on Form 10-K:

- Consolidated Balance Sheets as of December 31, 2022 and 2021
- Consolidated Statements of Operations for the three years in the period ended December 31, 2022
- Consolidated Statements of Shareholders' Equity or Deficit for the three years in the period ended December 31, 2022
- Consolidated Statements of Cash Flows for the three years in the period ended December 31, 2022

(a)(2) Consolidated Financial Statement Schedules.

Not applicable.

(a)(3); (b) Exhibits:

Exhibit No.	Description	Method of filing
2.1	Separation Agreement dated as of November 20, 2019 by and between Recro Pharma, Inc. and Baudax Bio, Inc.	Incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on November 26, 2019 (File No. 001-36329).
3.1	Second Amended and Restated Articles of Incorporation of Recro Pharma, Inc.	Incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on March 13, 2014 (File No. 001-36329).
3.2	Articles of Amendment to Second Amended and Restated Articles of Incorporation of Recro Pharma, Inc.	Incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on March 21, 2022 (File No. 001-36329).
3.3	Fourth Amended and Restated Bylaws of Societal CDMO, Inc.	Incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on March 21, 2022 (File No. 001-36329).
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of the Company.	Incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on December 13, 2022 (File No. 001-36329).
4.1†	Common Stock Purchase Warrant, dated November 17, 2017, in favor of Athyrium Opportunities III Acquisition LP.	Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on November 20, 2017 (File No. 001-36329).
4.2†	Common Stock Purchase Warrant, dated November 17, 2017, in favor of Athyrium Opportunities II Acquisition LP.	Incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on November 20, 2017 (File No. 001-36329).
4.3	Description of Securities	Filed herewith.

10.1†	Amended and Restated License and Supply Agreement, dated June 26, 2003, by and among Elan Corporation, plc (predecessor-in-interest to Recro Gainesville LLC) and Watson Laboratories, Inc.	Incorporated herein by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2015 (File No. 001-36329).
10.2	Supplemental Agreement, dated December 8, 2004, to Amended and Restated License and Supply Agreement, dated June 26, 2003, by and among Elan Corporation, plc (predecessor-in-interest to Recro Gainesville LLC) and Watson Laboratories, Inc.	Incorporated herein by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2015 (File No. 001-36329).
10.3	Supplemental Agreement No. 2, dated January 17, 2014, to Amended and Restated License and Supply Agreement, dated June 26, 2003, by and among Elan Corporation, plc (predecessor-in-interest to Recro Gainesville LLC) and Watson Laboratories, Inc.	Incorporated herein by reference to Exhibit 10.8 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2015 (File No. 001-36329).
10.4†	Supplemental Agreement No. 3, dated April 15, 2019, to Amended and Restated License and Supply Agreement, dated June 26, 2003, by and among Elan Corporation, plc (predecessor-in-interest to Recro Gainesville LLC) and Watson Laboratories, Inc.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 18, 2019 (File No. 001-36329).
10.5•	Asset Transfer and License Agreement, dated April 10, 2015, between Alkermes Pharma Ireland Limited and DV Technology, Inc.	Incorporated herein by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on May 12, 2015 (File No. 001-36329).
10.6•	Amendment to Asset Transfer and License Agreement, dated December 23, 2015, between Alkermes Pharma Ireland Limited and Recro Gainesville LLC.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 23, 2015 (File No. 001-36329).
10.7•	Second Amendment to Asset Transfer and License Agreement, dated December 20, 2018, between Alkermes Pharma Ireland Limited and Recro Gainesville LLC.	Incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on December 28, 2018 (File No. 001-36329).
10.8†	Manufacturing and Supply Agreement, dated as of February 8, 2019, by and between Recro Gainesville LLC and Novartis Pharma AG.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K/A filed on March 6, 2019 (File No. 001-3632).
10.9	License and Supply Agreement, dated as of January 1, 2014, by and between Alkermes Pharma Ireland Limited and Kremers Urban Pharmaceuticals, Inc.	Incorporated herein by reference to Exhibit 10.29 to the Company's Annual Report on Form 10-K filed on March 4, 2020 (File No. 001-36329).
10.10	Amendment No. 1 to License and Supply Agreement, dated as of September 6, 2018, by and between Recro Gainesville LLC and Kremers Urban Pharmaceuticals, Inc.	Incorporated herein by reference to Exhibit 10.30 to the Company's Annual Report on Form 10-K filed on March 4, 2020 (File No. 001-36329).
10.11	Amendment No. 2 to License and Supply Agreement, dated as of November 5, 2020 by and among Recro Gainesville LLC, Kremers Urban Pharmaceuticals, Inc. and Lannett Company, Inc.	Incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on November 10, 2020 (File No. 001-36329).
10.12	Amendment No. 3 to License and Supply Agreement, dated as of July 1, 2022 by and among Societal CDMO Gainesville LLC and Lannett Company, Inc.	Incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 10, 2022 (File No. 001-36329).

10.13	Stock Issuance Agreement, dated as of February 19, 2021 by and between Recro Pharma, Inc., Athyrium Opportunities II Acquisition LP and Athyrium Opportunities III Acquisition LP.	Incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on February 23, 2021 (File No. 001-36329).
10.14	Unit Purchase Agreement, dated August 13, 2021, by and among Recro Pharma, Inc., IriSys, LLC, the Sellers (as defined therein), and IriSys, Inc. as the Seller's Representative	Incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on August 13, 2021 (File No. 001-36329).
10.15	Form of Subordinated Promissory Note	Incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on August 13, 2021 (File No. 001-36329).
10.16	Purchase and Sale Agreement and Joint Escrow Instructions dated August 11, 2022, by and among Societal CDMO Gainesville, LLC, a Massachusetts limited liability company and Weekley Homes, LLC, a Delaware limited liability company.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 16, 2022 (File No. 001-36329).
10.17	Purchase and Sale Agreement, dated as of December 9, 2022, by and between Societal CDMO Gainesville, LLC and Tenet Equity Funding SPE Gainesville, LLC	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 12, 2022 (File No. 001-36329).
10.18	Lease Agreement dated December 14, 2022, by and between Societal CDMO Gainesville, LLC and Tenet Equity Funding SPE Gainesville, LLC	Filed herewith.
10.19	Credit Agreement, dated as of December 12, 2022, by Societal CDMO, Inc. in favor of RBC Capital Markets, LLC	Incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed on December 12, 2022 (File No. 001-36329).
10.20•	Recro Pharma, Inc. 2018 Amended and Restated Equity Incentive Plan.	Incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on May 9, 2018 (File No. 001-36329).
10.21•	Form of Non-Qualified Stock Option Inducement Award Agreement	Incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 9, 2021 (File No. 001-36329).
10.22•	Form of Inducement Award Agreement for Restricted Stock Units	Incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 9, 2021 (File No. 001-36329).
10.23•	Form of Non-Qualified Stock Option Award Agreement	Incorporated herein by reference to Exhibit 10.26 to the Company's Annual Report on Form 10-K filed on February 26, 2021 (File No. 001-36329).
10.24•	Form of Award Agreement for Restricted Stock Units	Incorporated herein by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-K filed on February 26, 2021 (File No. 001-36329).
10.25•	Form of Award Agreement for Restricted Stock Units (performance-based)	Incorporated herein by reference to Exhibit 10.28 to the Company's Annual Report on Form 10-K filed on February 26, 2021 (File No. 001-36329).

10.26•	Employment Agreement between Recro Pharma, Inc. and J. David Enloe, Jr., dated December 15, 2020.	Incorporated by reference to exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 21, 2020 (File No. 001-36329).
10.27•	Employment Agreement between Recro Pharma, Inc. and Ryan Lake, dated December 15, 2020.	Incorporated by reference to exhibit 10.2 to the Company's Current Report on Form 8-K filed on December 21, 2020 (File No. 001-36329).
21.1	Subsidiaries of Societal CDMO, Inc.	Filed herewith.
23.1	Consent of KPMG LLP, Independent Registered Public Accounting Firm.	Filed herewith.
31.1	Rule 13a-14(a)/15d-14(a) certification of Principal Executive Officer.	Filed herewith.
31.2	Rule 13a-14(a)/15d-14(a) certification of Principal Financial Officer.	Filed herewith.
32.1	Section 1350 certification, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
101 SCH	Inline XBRL Taxonomy Extension Schema	Filed herewith.
101 CAL	Inline XBRL Taxonomy Extension Calculation Linkbase	Filed herewith.
101 DEF	Inline XBRL Taxonomy Extension Definition Linkbase	Filed herewith.
101 LAB	Inline XBRL Taxonomy Extension Label Linkbase	Filed herewith.
101 PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith.
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)	Filed herewith.

• Management contract or compensatory plan or arrangement.

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 406 under the Securities Act of 1933.

(c) Not applicable

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: March 1, 2023

SOCIETAL CDMO, INC.

By: /s/ J. David Enloe, Jr.
J. David Enloe, Jr.
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, Annual Report on Form 10-K has been signed by the following persons in the capacities held on the dates indicated.

Signature	Title	Date
/s/ J. David Enloe, Jr. J. David Enloe, Jr.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 1, 2023
/s/ Ryan D. Lake Ryan D. Lake	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 1, 2023
/s/ William L. Ashton William L. Ashton	Director	March 1, 2023
/s/ Michael Berelowitz Michael Berelowitz	Director	March 1, 2023
/s/ Elena Cant Elena Cant	Director	March 1, 2023
/s/ Winston J. Churchill Winston J. Churchill	Director	March 1, 2023
/s/ James C. Miller James C. Miller	Director	March 1, 2023
/s/ Laura L. Parks Laura L. Parks	Director	March 1, 2023
/s/ Bryan M. Reasons Bryan M. Reasons	Director	March 1, 2023
/s/ Wayne B. Weisman Wayne B. Weisman	Director	March 1, 2023

SOCIETAL CDMO, INC. AND SUBSIDIARIES

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors
Societal CDMO, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Societal CDMO, Inc. and subsidiaries (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations, shareholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2022, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of intbernal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Variable consideration for profit-sharing revenue

As discussed in Note 2 to the consolidated financial statements, the Company earns sales-based profit-sharing or royalty consideration, collectively referred to as profit-sharing revenue, which is computed based on the net product sales of the commercial partner. For arrangements that include product sales and sales-based profit-sharing where the license for intellectual property is not deemed to be the predominant item to which the profit-sharing relates, the profit-sharing is variable consideration and the Company recognizes revenue, including an estimate of profit-sharing, upon transfer of control of the manufactured product. In these cases, significant judgment is required to calculate the estimated variable consideration from such profit-sharing using the expected value method based on historical commercial partner pricing and deductions. Estimated variable consideration is partially constrained due to the uncertainty of price adjustments made by the Company's commercial partners, which are outside of the Company's control. Factors causing price adjustments by the Company's commercial partners include increased competition in the products' markets, mix of volume between the commercial partners' customers, and changes in government pricing. The Company reported total revenue of $90.2 million for the year ended December 31, 2022, which included profit-sharing revenue.

We identified the evaluation of the estimate of the variable consideration for arrangements that include sales-based profit-sharing where the license for intellectual property is not deemed to be the predominant item as a critical audit matter. A high degree of auditor judgment was required to evaluate the Company's determination of the constraint due to the uncertainty of price adjustments made by the Company's commercial partners in response to market conditions.

The following are the primary procedures we performed to address this critical audit matter. We evaluated the design of certain internal controls related to the determination of the constraint used to estimate variable consideration. We evaluated the Company's ability to estimate variable consideration by comparing the actual amount of profit-sharing revenue realized by the Company to its historical estimates. We obtained and inspected third party market data regarding the effect of market conditions on the commercial partners and potential price adjustments they may offer with respect to their products, and assessed how the Company considered such market conditions in its determination of the constraint.

/s/ KPMG LLP

We have served as the Company's auditor since 2009.

Philadelphia, Pennsylvania
March 1, 2023

SOCIETAL CDMO, INC. AND SUBSIDIARIES
Consolidated Balance Sheets

(amounts in thousands, except share and per share data)	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 14,995	$ 25,217
Accounts receivable, net	15,950	11,913
Contract assets	8,724	8,565
Inventory	10,301	8,917
Prepaid expenses and other current assets	2,848	2,917
Assets held for sale	2,768	—
Total current assets	55,586	57,529
Property, plant and equipment, net	50,365	51,708
Operating lease asset	5,491	5,924
Intangible assets, net	2,928	3,833
Goodwill	41,077	41,077
Other assets	1,996	246
Total assets	$ 157,443	$ 160,317
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 1,466	$ 2,085
Current portion of debt	7,577	2,039
Current portion of operating lease liability	1,079	1,055
Accrued expenses and other current liabilities	12,686	12,556
Total current liabilities	22,808	17,735
Debt, net of current portion	30,967	95,496
Operating lease liability, net of current portion	4,584	4,932
Other liabilities	39,225	90
Total liabilities	97,584	118,253
Commitments and contingencies (note 7)		
Shareholders' equity:		
Convertible preferred stock, $0.01 par value. 10,000,000 shares authorized, 450,000 shares issued and outstanding at December 31, 2022, none issued or outstanding at December 31, 2021	4,350	—
Common stock, $0.01 par value. 95,000,000 shares authorized, 84,588,868 and 46,681,453 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	846	467
Additional paid-in capital	320,298	287,351
Accumulated deficit	(265,635)	(245,754)
Total shareholders' equity	59,859	42,064
Total liabilities and shareholders' equity	$ 157,443	$ 160,317

See accompanying notes to consolidated financial statements.

SOCIETAL CDMO, INC. AND SUBSIDIARIES
Consolidated Statements of Operations

(amounts in thousands, except share and per share data)	Year ended December 31, 2022	2021	2020
Revenue	$ 90,214	$ 75,360	$ 66,499
Operating expenses:			
Cost of sales (excluding amortization of intangible assets)	67,076	55,537	54,134
Selling, general and administrative	21,954	18,374	18,124
Amortization of intangible assets	905	1,037	2,583
Total operating expenses	89,935	74,948	74,841
Operating income (loss)	279	412	(8,342)
Interest expense	(14,059)	(15,134)	(19,159)
(Loss) gain on extinguishment of debt	(4,996)	3,352	—
Loss before income taxes	(18,776)	(11,370)	(27,501)
Income tax expense	1,105	—	—
Net loss	$ (19,881)	$ (11,370)	$ (27,501)
Loss per share, basic and diluted	$ (0.34)	$ (0.26)	$ (1.16)
Weighted average shares outstanding, basic and diluted	57,877,920	44,117,473	23,744,313

See accompanying notes to consolidated financial statements.

SOCIETAL CDMO, INC. AND SUBSIDIARIES

Consolidated Statements of Shareholders' Equity (Deficit)

(amounts in thousands, except share data)	Convertible preferred stock Shares	Convertible preferred stock Amount	Common stock Shares	Common stock Amount	Additional paid-in capital	Accumulated deficit	Total
Balance, December 31, 2019	—	$ —	23,312,928	$ 233	$ 199,938	$ (206,883)	$ (6,712)
Issuance of stock, net of costs	—	—	4,690,972	47	10,686	—	10,733
Stock-based compensation expense	—	—	—	—	10,068	—	10,068
Exercise of stock options, net	—	—	142,669	1	273		274
Vesting of restricted stock units, net	—	—	454,789	5	(1,141)	—	(1,136)
Revaluation of warrants	—	—	—	—	174		174
Net loss	—	—	—	—	—	(27,501)	(27,501)
Balance, December 31, 2020	—	—	28,601,358	286	219,998	(234,384)	(14,100)
Fair value of shares issuable to former equity holders of IriSys, net of costs	—	—	—	—	20,328	—	20,328
Issuance of stock, net of costs	—	—	17,535,752	175	41,268	—	41,443
Stock-based compensation expense	—	—	—	—	6,514	—	6,514
Vesting of restricted stock units, net	—	—	544,263	6	(757)	—	(751)
Exercise of stock options, net	—	—	80	—	—	—	—
Net loss	—	—	—	—	—	(11,370)	(11,370)
Balance, December 31, 2021	—	—	46,681,453	467	287,351	(245,754)	42,064
Issuance of stock, net of costs	450,000	4,350	37,144,455	371	27,694	—	32,415
Stock-based compensation expense	—	—	—	—	5,426	—	5,426
Vesting of restricted stock units, net	—	—	762,444	8	(173)	—	(165)
Exercise of stock options, net	—	—	516	—	—	—	—
Net loss	—	—	—	—	—	(19,881)	(19,881)
Balance, December 31, 2022	450,000	$ 4,350	84,588,868	$ 846	$ 320,298	$ (265,635)	$ 59,859

See accompanying notes to consolidated financial statements.

SOCIETAL CDMO, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows

(amounts in thousands)	Year ended December 31, 2022	2021	2020
Cash flows from operating activities, continuing operations:			
Net loss	$ (19,881)	$ (11,370)	$ (27,501)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities, continuing operations:			
Stock-based compensation expense	5,426	6,514	10,068
Non-cash interest expense	4,845	5,815	5,510
Depreciation expense	7,413	6,531	5,964
Impairment expense	—	—	966
Amortization of intangible assets	905	1,037	2,583
Deferred income tax expense	1,015	—	—
Loss (gain) on extinguishment of debt	4,996	(3,352)	—
Changes in operating assets and liabilities:			
Accounts receivable	(4,037)	(1,971)	5,356
Contract assets	(159)	(730)	1,521
Inventory	(1,384)	3,380	3,460
Prepaid expenses and other assets	305	120	4
Accrued interest	(2,278)	2,505	—
Accounts payable, accrued expenses and other liabilities	(810)	2,379	1,308
Net cash (used in) provided by operating activities, continuing operations	(3,644)	10,858	9,239
Cash flows from investing activities:			
Acquisition of IriSys, net of cash required	—	(24,002)	—
Purchases of property and equipment	(8,351)	(5,289)	(7,603)
Net cash used in investing activities	(8,351)	(29,291)	(7,603)
Cash flows from financing activities:			
Proceeds from issuance of stock, net of costs	33,030	32,103	11,094
Proceeds from issuance of debt	36,900	—	4,416
Proceeds from sale-leaseback liability (see note 9)	37,250	—	—
Payment of debt principal	(103,039)	(10,100)	(10,190)
Payment of financing costs	(2,203)	(1,362)	(310)
Net payments related to vesting of restricted stock units	(165)	(751)	(1,136)
Net proceeds related to exercise of stock options	—	—	274
Net cash provided by financing activities	1,773	19,890	4,148
Net (decrease) increase in cash and cash equivalents from continuing operations	(10,222)	1,457	5,784
Cash flows used in operating activities, discontinued operations	—	—	(1,172)
Cash and cash equivalents, beginning of period	25,217	23,760	19,148
Cash and cash equivalents, end of period	$ 14,995	$ 25,217	$ 23,760
Supplemental disclosures of cash flow information:			
Cash paid for interest	$ 12,574	$ 7,238	$ 13,945
Purchases of property, plant and equipment included in accrued expenses and accounts payable	1,384	1,045	1,244
Deferred financing costs included in accounts payable and accrued expenses	1,359	—	—
Offering costs included in accounts payable and accrued expenses	527	—	—
Reclassification of deferred financing costs to equity	88	—	361
Fair value of shares issuable to former equity holders of IriSys	—	20,931	—
Fair value of note issued to former equity holders of IriSys	—	5,240	—
Issuance of common stock to reduce debt principal and accrued exit fees	—	6,060	—
Issuance of common stock to settle interest obligations	—	3,211	—

See accompanying notes to consolidated financial statements.

(1) Background

Societal CDMO, Inc. (the "Company") was incorporated in the Commonwealth of Pennsylvania on November 15, 2007 as Recro Pharma, Inc. Effective March 21, 2022, Recro Pharma, Inc changed its name to Societal CDMO, Inc. to reflect the corporate transformation that had taken place primarily as a result of its acquisition and successful integration of IriSys, LLC ("IriSys") into the organization. The Company is a bi-coastal contract development and manufacturing organization with capabilities spanning pre-investigational new drug development to commercial manufacturing and packaging for a wide range of therapeutic dosage forms with a primary focus in the area of small molecules. With an expertise in solving complex manufacturing problems, the Company provides therapeutic development, end-to-end regulatory support, clinical and commercial manufacturing, aseptic fill/finish, lyophilization, packaging and logistics services to the global pharmaceutical market.

The Company has incurred net losses since inception and has an accumulated deficit of $265,635 as of December 31, 2022, which is primarily related to the activities of its former research and development business, which was spun-out in 2019. The Company's future operations are highly dependent on the profitability of its development and manufacturing operations. Management believes that it is probable that the Company will be able to meet its obligations as they become due within at least one year after the date financial statements included herein are issued.

(2) Summary of significant accounting principles

Basis of presentation and principles of consolidation

The accompanying consolidated financial statements of the Company and its subsidiaries have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). The Company's consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated. The Company has determined that it operates in a single segment.

Reclassification

The Company reclassified certain prior year amounts on the consolidated balance sheet to conform to the current year presentation. These reclassifications had no impact on the previously reported total assets, liabilities or shareholders' equity.

Use of estimates

The preparation of financial statements and the notes to the financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from such estimates.

Business combinations

The Company measures the purchase price paid for acquired companies based on fair value and allocates that purchase price to the assets acquired and liabilities assumed based on their estimated fair values. Valuations are performed to assist in determining the fair values of assets acquired and liabilities assumed, which requires management to make estimates and assumptions, in particular with respect to intangible assets. Management makes estimates of fair value based upon assumptions believed to be reasonable. These estimates are based in part on historical experience and information obtained from the acquired companies and expectations of future cash flows. Costs associated with business combinations are expensed as incurred as selling, general and administrative expenses.

Cash and cash equivalents

Cash and cash equivalents represent cash in banks and highly liquid short-term investments that have maturities of three months or less when acquired. These highly liquid short-term investments are both readily convertible to known amounts of cash and so near to their maturity that they present insignificant risk of changes in value due to changes in interest rates.

Accounts receivable, net

Accounts receivable generally represent amounts billed for services provided under our customer contracts and are recorded at the invoiced amount net of an allowance for credit losses, if necessary. We apply judgment in assessing the ultimate realization of our receivables, and we estimate an allowance for credit losses based on various factors, such as the aging of our receivables, historical experience, and the financial condition of our customers. The allowance for credit losses was not material as of the balance sheet dates presented.

Inventory

Inventory is stated at the lower of cost or net realizable value. Included in inventory are raw materials and work-in-process used in the production of commercial products. Items are issued out of inventory using the first-in, first-out method.

Adjustments to inventory are determined at the raw materials, work-in-process, and finished good levels to reflect obsolescence or impaired balances. Factors influencing inventory obsolescence include changes in demand, product life cycle, product pricing, physical deterioration and quality concerns.

Property, plant and equipment, net

Property, plant and equipment are recorded at cost less accumulated depreciation and amortization. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the assets, which are as follows: three to ten years for furniture, office and computer equipment; six to ten years for manufacturing equipment; 40 years for buildings; and the shorter of the lease term or useful life for leasehold improvements. Repairs and maintenance costs are expensed as incurred. The Company reviews the carrying value of property, plant and equipment for recoverability whenever events occur or changes in circumstances indicate that the carrying amount of individual assets or asset groups may not be recoverable.

The Company considers assets to be held for sale when (i) management commits to a plan to sell the asset; (ii) the asset is available for immediate sale in its present condition; (iii) the asset is actively being marketed for sale at a price that is reasonable given the estimate of current market value; and (iv) the sale is probable and will be completed within one year. Upon designation of an asset as held for sale, the Company records the asset's value at the lower of its carrying value plus selling costs or its estimated net realizable value.

Goodwill and intangible assets

Goodwill represents the excess of purchase price over the fair value of net assets acquired by the Company in a business combination. Goodwill is not amortized but assessed for impairment on an annual basis or more frequently if impairment indicators exist.

The impairment analysis for goodwill consists of an optional qualitative assessment potentially followed by a quantitative analysis. If the Company determines that the carrying value of its reporting unit exceeds its fair value, an impairment charge is recorded for the excess.

The Company performs its annual goodwill impairment test as of November 30th, or whenever an event or change in circumstance occurs that would require reassessment of the impairment of goodwill. In performing the evaluation, the Company assesses qualitative factors such as overall financial performance, actual and anticipated changes in industry and market conditions, and competitive environments. As a result of the most recent annual goodwill impairment test, the Company determined that there was no impairment of goodwill.

Definite-lived intangible assets are amortized on a straight-line basis over their estimated useful life. The Company is required to review the carrying value of definite-lived intangible assets for recoverability whenever events occur or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable.

Contingencies

The Company's business exposes it to various contingencies including compliance with regulations, legal exposures and other matters. Loss contingencies are reflected in the financial statements based on management's assessments of their expected outcome or resolution:

- They are recognized as liabilities on the balance sheet if the potential loss is probable and the amount can be reasonably estimated.
- They are disclosed if the potential loss is material and considered at least reasonably possible.

Significant judgment is required to determine probability and whether the amount can be reasonably estimated. Due to uncertainties related to these matters, accruals are based only on the information available at the time. As additional information becomes available, the Company reassesses potential liabilities and may revise previous estimates.

Revenue recognition

The Company generates revenues from manufacturing, packaging, research and development and related services for multiple pharmaceutical companies.

Manufacturing

Manufacturing and other related services revenue is recognized upon transfer of control of a product to a customer, generally upon shipment, based on a transaction price that reflects the consideration the Company expects to be entitled to as specified in the agreement with the commercial partner, which could include variable consideration such as pricing and volume-based adjustments.

Profit-sharing

In addition to manufacturing and packaging revenue, certain customers who use our technologies are subject to agreements that provide us intellectual property sales-based profit-sharing and/or royalties consideration, collectively referred to as profit-sharing, computed on the net product sales of the commercial partner. Profit-sharing revenues are generally recognized under the terms of the applicable license, development and/or supply agreement. The Company has determined that in its arrangements, the license for intellectual property is not the predominant item to which the profit-sharing relates, so the Company recognizes revenue upon transfer of control of the manufactured product. In these cases, significant judgment is required to calculate the estimated variable consideration from such profit-sharing using the expected value method based on historical commercial partner pricing and deductions. Estimated variable consideration is partially constrained due to the uncertainty of price adjustments made by the Company's commercial partners, which are outside of the Company's control. Factors causing price adjustments by the Company's commercial partners include increased competition in the products' markets, mix of volume between the commercial partners' customers, and changes in government pricing.

Research and development

Research and development revenue includes services associated with formulation, process development, clinical trials materials services, as well as custom development of manufacturing processes and analytical methods for a customer's non-clinical, clinical and commercial products. Such revenues are recognized at a point in time or over time depending on the nature and particular facts and circumstances associated with the contract terms.

In contracts that specify milestones, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. Milestone payments related to arrangements under which the Company has continuing performance obligations are deferred and recognized over the period of performance. Milestone payments that are not within the Company's control, such as submission for approval to regulators by a commercial partner or approvals from regulators, are not considered probable of being achieved until those submissions are submitted by the customer or approvals are received.

In contracts that require revenue recognition over time, the Company utilizes input or output methods, depending on the specifics of the contract, that compare the cumulative work-in-process to date to the most current estimates for the entire performance obligation. Under these contracts, the customer typically owns the product details and process, which have no alternative use. These projects are customized to each customer to meet its specifications, and typically only one performance obligation is included. Each project represents a distinct service that is sold separately and has stand-alone value to the customer. The customer also retains control of its product as the product is being created or enhanced by the Company's services and can make changes to its process or specifications upon request.

Contract assets represent revenue recognized for performance obligations completed or in process before an unconditional right to payment exists, and therefore invoicing or associated reporting from the customer regarding the computation of the net product sales has not yet occurred. Contract liabilities represent payments received from customers prior to the completion of associated performance obligations.

Concentration of credit risk

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash, cash equivalents and accounts receivable. The Company manages its cash and cash equivalents based on established guidelines relative to diversification and maturities to maintain safety and liquidity.

The Company's accounts receivable balances are primarily concentrated among two customers with balances of 64%. If any of these customers' receivable balances should be deemed uncollectible, it could have a material adverse effect on the Company's results of operations and financial condition.

The Company is dependent on its relationships with a small number of commercial partners. The Company's four largest customers generated 77% of revenues in 2022 while the Company's three largest customers generated 82% of revenues in 2021.

Stock-based compensation expense

The Company measures employee stock-based awards at grant-date fair value and recognizes employee compensation expense on a straight-line basis over the vesting period of the award. The Company accounts for forfeitures as they occur.

Determining the appropriate fair value of stock options requires the use of subjective assumptions, including the expected life of the option and expected stock price volatility. The Company uses the Black-Scholes option pricing model to value its stock option awards. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. As a result, if factors change and/or management uses different assumptions, stock-based compensation expense could be materially different for future awards.

The expected life of stock options was estimated using the "simplified method," which is based on the average of the vesting tranches and the contractual life of each grant. For stock price volatility, the Company uses the historical volatility of its publicly traded stock in order to estimate future stock price trends. The risk-free interest rate is based on U.S. Treasury notes with a term approximating the expected life of the option.

Upon exercise of stock options or vesting of restricted stock units, the holder may elect to cover tax withholdings by forfeiting shares of an equivalent value. In such cases, the Company issues net new shares to the holder, pays the tax withholding on behalf of the participant and presents the payment similar to a capital distribution: a reduction to additional paid-in-capital and a financing cash outflow in the consolidated financial statements.

Income taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis, operating losses and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date.

In assessing the realizability of net deferred tax assets, the Company considers all relevant positive and negative evidence in determining whether it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The realization of the gross deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of the net operating loss carryforwards. A full valuation allowance was recorded as of December 31, 2022 and December 31, 2021.

Unrecognized income tax benefits represent income tax positions taken on income tax returns that have not been recognized in the consolidated financial statements. The Company recognizes the benefit of an income tax position only if it is more likely than not (greater than 50%) that the tax position will be sustained upon tax examination, based solely on the technical merits of the tax position. Otherwise, no benefit is recognized. The tax benefits recognized are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. The Company does not anticipate significant changes in the amount of unrecognized income tax benefits over the next year.

Leases

The Company determines under U.S. GAAP if an arrangement is a lease at inception. The arrangement is a lease if it conveys the right to the Company to control the use of identified property, plant, or equipment for a period of time in exchange for consideration. Options to extend the lease are included in the lease term if the options are reasonably certain to be exercised. Operating lease expense is recognized on a straight-line basis over the lease term. In a sale-leaseback transaction, the Company determines under U.S. GAAP if the transaction meets the requirements of a sale and purchase. If the Company determines that it did not relinquish control of the assets to the buyer-lessor, it does not qualify for sale-leaseback accounting.

Operating lease balances are presented as separate captions on the balance sheets. Finance lease assets are included in property, plant and equipment. Finance lease liabilities are included in other liabilities.

Income or loss per share

Net loss per common share is computed using the two-class method required due to the participating nature of the Series A Convertible Preferred Stock (as defined and discussed in note 10) given the rights to participate in dividends if declared on common stock. The two-class method is an earnings allocation formula that treats participating securities as having rights to earnings that would otherwise have been available to common stockholders. In addition, as these securities are participating securities, the Company is required to calculate diluted net income or loss per share under the if-converted and treasury stock method in addition to the two-class method and utilize the most dilutive result. In periods where there is a net loss, no allocation of undistributed net loss to the Series A Convertible Preferred stockholders is performed as the holders of these securities are not contractually obligated to participate in the Company's losses.

Basic income or loss per share is determined by dividing net income or loss (the numerator) by the weighted average common shares outstanding during the period (the denominator). Additionally, the weighted average common shares outstanding for the year ended December 31, 2021 include 9,302,718 shares issuable to the former equity holders of IriSys, since the acquisition date.

To calculate diluted income or loss per share, the numerator and denominator are adjusted to eliminate the income or loss and the dilutive effects on shares, respectively, caused by outstanding common stock options, warrants and unvested restricted stock units, using the treasury stock method, if the inclusion of such instruments would be dilutive.

For all years presented, the Company incurred a net loss. In periods of net loss, the inclusion of dilutive securities would be antidilutive because it would reduce the amount of loss incurred per share. As a result, no additional dilutive shares were included in diluted loss per share, and there were no differences between basic and diluted loss per share.

The following table presents the potentially dilutive securities that were excluded from the computations of diluted loss per share:

	Year ended December 31,		
	2022	2021	2020
Restricted stock units	1,583,469	731,525	684,852
Stock options	7,317,274	4,645,109	3,577,605
Warrants	362,030	348,664	348,664

Amounts in the table above reflect the common stock equivalents of the noted instruments.

(3) Inventory

The following table presents the components of inventory:

	December 31, 2022	December 31, 2021
Raw materials	$ 4,318	$ 3,038
Work in process	3,689	3,363
Finished goods	2,294	2,516
Inventory	$ 10,301	$ 8,917

(4) Goodwill and other intangible assets

The following table presents the rollforward of goodwill:

Balance, December 31, 2020	$ 4,319
Acquisition of IriSys	36,758
Balance, December 31, 2021 and 2022	$ 41,077

The following table presents the components of other intangible assets:

	December 31, 2022			December 31, 2021		
	Gross value	Accumulated amortization	Carrying value	Gross value	Accumulated amortization	Carrying value
Customer relationships	$ 18,900	$ 16,188	$ 2,712	$ 18,900	$ 15,685	$ 3,215
Backlog	460	261	199	460	73	387
Trademarks and tradenames	310	293	17	310	79	231
Total	$ 19,670	$ 16,742	$ 2,928	$ 19,670	$ 15,837	$ 3,833

The following table presents estimated future amortization of other intangible assets:

Twelve months ending December 31,	
2023	$ 687
2024	501
2025	486
2026	486
2027	486
Thereafter	282
Total	$ 2,928

(5) Property, plant and equipment, net

The following table presents the components of property, plant and equipment:

	December 31, 2022	December 31, 2021
Land	$ 604	$ 3,263
Building and improvements	22,751	22,717
Furniture, office and computer equipment	6,388	6,213
Manufacturing equipment	58,039	49,687
Construction in process	7,024	6,856
Property, plant and equipment, gross	94,806	88,736
Less: accumulated depreciation	(44,441)	(37,028)
Property, plant and equipment, net	$ 50,365	$ 51,708

Interest expense capitalized to construction in process was $1,195 in 2022 and $424 in 2021.

In September 2022, the Company signed a sales and purchase agreement to sell approximately 121 acres of land adjacent to its Gainesville, Georgia manufacturing campus for expected proceeds of $9,075. The land was determined to be held for sale at December 31, 2022 and reclassified at cost to other current assets with a carrying value of $2,659. The sale of the land is subject to customary closing conditions for transactions of this type, including completion of title and environmental due diligence and receipt of certain zoning approvals and permits, which remained to be satisfied at December 31, 2022.

In December 2022, the Company sold its commercial manufacturing campus in Gainesville, Georgia for a purchase price of $39,000 and the Company entered into a lease agreement under which the Company agreed to lease back the property for an initial term of 20 years. The Company determined that it did not relinquish control of the assets to the buyer-lessor. Therefore, the Company accounted for the transactions as failed sale-leaseback whereby the Company continues to depreciate the assets and recorded a financing obligation for the consideration received from the buyer-lessor. See note 9 for additional information.

(6) Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consist of the following:

	December 31, 2022	December 31, 2021
Payroll and related costs	$ 4,276	$ 5,717
Accrued transaction costs	3,653	—
Contract liabilities (see note 11)	2,211	2,308
Property, plant and equipment	934	663
Professional and consulting fees	356	552
Accrued interest	227	2,505
Other	1,029	811
Total	$ 12,686	$ 12,556

Accrued transaction costs include costs incurred related to the refinancing completed in December 2022 which included the sale and subsequent leaseback of the Company's commercial manufacturing campus located in Gainesville, Georgia (see note 9), the issuance of common and preferred stock, a borrowing of $36,900 under a new term loan with Royal Bank of Canada (see note 8) and a one-time cash transaction bonus.

(7) Commitments and contingencies

Litigation

The Company is involved, from time to time, in various claims and legal proceedings arising in the ordinary course of its business. Except as disclosed below, the Company is not currently a party to any such claims or proceedings that, if decided adversely to it, would either individually or in the aggregate have a material adverse effect on its business, financial condition or results of operations.

On May 31, 2018, a securities class action lawsuit was filed against the Company and certain of its officers and directors (collectively, the "Defendants") in the U.S. District Court for the Eastern District of Pennsylvania (the "Court") (Case No. 2:18-cv-02279-MMB) that purported to state a claim for alleged violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder, based on statements made by the Company concerning the New Drug Application ("NDA") for IV meloxicam. The complaint sought unspecified damages, interest, attorneys' fees and other costs. In December 2022, a settlement was reached in the litigation, and the costs of the settlement were covered by Baudax Bio, Inc. pursuant to the terms of the separation agreement covering the spin-out of Baudax Bio, Inc. from our business in 2019.

On July 2, 2022, a product liability lawsuit was filed against the Company and various other defendants in the State Court of Cobb County, Georgia that claimed injuries and damages caused by Plaintiff Jakob Cuble's alleged ingestion of, among other things, Focalin XR. The complaint seeks compensatory and punitive damages. On July 7, 2022, and prior to the Company being served with the Complaint, a co-defendant removed the matter to the United States District Court for the Northern District of Georgia, Atlanta Division. The Company filed its responsive pleading on August 2, 2022. In September 2022, the case was remanded to the State Court of Cobb County, Georgia, where it presently pends. The Company believes that the lawsuit is without merit and intends to vigorously defend against it.

Purchase commitments

As of December 31, 2022, the Company had outstanding cancelable and non-cancelable purchase commitments in the aggregate amount of $9,732 related to inventory, capital expenditures and other goods and services.

Employment agreements and certain other contingencies

The Company has entered into employment agreements with each of its named executive officers that provide for, among other things, severance commitments of up to $1,303 should the Company terminate the named executive officers for convenience or if certain events occur following a change in control. In addition, the Company is subject to other contingencies of up to $3,772 in the aggregate if certain events occur following a change in control.

(8) Debt

The following table presents the components and classification of debt:

	December 31, 2022	December 31, 2021
Debt principal:		
Term loan under Credit Agreement	$ 36,900	$ —
Term loans with Athyrium	—	100,000
Note with former equity holder of IriSys	4,078	6,117
Other	339	339
Debt principal	41,317	106,456
Debt adjustments:		
Unamortized deferred issuance costs	(2,476)	—
Unamortized deferred issuance costs with Athyrium	—	(8,896)
Exit fee accretion	—	669
Unamortized original discount	(297)	(694)
Carrying value of debt	$ 38,544	$ 97,535
Current portion of debt	$ 7,577	$ 2,039
Debt, net of current portion	30,967	95,496
Carrying value of debt	$ 38,544	$ 97,535

The following table presents the future maturity of debt principal:

Twelve months ending December 31,	
2023	$ 7,577
2024	4,823
2025	28,626
2026	39
2027	46
Thereafter	206
Total debt principal	$ 41,317

Term loan under Credit Agreement

The Company is currently party to a credit agreement (the "Credit Agreement") with Royal Bank of Canada. The Credit Agreement has been fully drawn in the form of a term loan of $36,900. The outstanding principal amount will be repaid in equal quarterly payments totaling $1,845 in 2023, $2,768 in 2024 and $3,690 in 2025, with the remaining principal balance due December 16, 2025. If the Company completes a sale of certain real property by December 14, 2023 and makes the $10,000 principal repayment disclosed below, the quarterly principal payments will be reduced proportionately to the reduction in principal.

Subject to certain exceptions, the Company is required to make mandatory prepayments with the cash proceeds received in respect of asset sales, extraordinary receipts and debt issuances, upon a change of control and specified other events. Additionally, the Company is obligated to repay $10,000 of principal by December 14, 2023 upon the sale of certain real property adjacent to its Gainesville, Georgia manufacturing campus (see note 5). If that property is not sold by December 14, 2023, the Company will be required to pay a fee of $369 and increase each of its quarterly principal payments by $231 until that property is sold and the $10,000 principal payment is made. Because the Company concluded that the sale of the property is probable as of December 31, 2022, an additional $3,693 of debt principal has been presented as current, representing the carrying value of the current asset held for sale plus the $925 excess of the principal payment over the expected proceeds from the asset.

The Credit Agreement also includes certain financial covenants that the Company will need to satisfy on a quarterly basis, including: (i) maintaining a net leverage ratio less than 3.75:1.00, stepping down to 2.75:1.00 over time; (ii) maintaining a fixed charge coverage ratio greater than 1.15:1.00; and (iii) maintaining no less than $4,000 cash and cash equivalents on hand, stepping up to $5,000 over time. As of December 31, 2022, the Company was in compliance with its covenants under the Credit Agreement.

In connection with the Credit Agreement, the Company has paid financing costs. These costs are being recognized in interest expense using the effective interest method over the term of the Credit Agreement, resulting in non-cash interest expense of $35 in 2022.

The Credit Agreement bears interest at a floating rate equal to the three-month term Secured Overnight Financing Rate, or SOFR, with an initial floor of 1.00%, plus an applicable margin that is equal to 4.50% per annum for the first year, 5.00% for the second year and 5.50% for the third year, with quarterly interest payments due until maturity. At December 31, 2022, the overall effective interest rate, including cash paid for interest and non-cash interest expense, was 11.7%.

Historical term loans with Athyrium

The Company was previously party to a credit agreement with Athyrium Opportunities III Acquisition LP ("Athyrium Credit Agreement"). The Athyrium Credit Agreement was fully drawn in the form of $100,000 of term loans at an interest rate equal to the three-month LIBOR rate, with a 1% floor plus 8.25% per annum and maturing on December 31, 2023.

The Company used the proceeds from the Credit Agreement, along with the proceeds from the sale-leaseback transaction (see note 9) and the issuance of preferred and common stock (see note 10) to repay in full all outstanding indebtedness under the Athyrium Credit Agreement, including accrued and unpaid interest and the required exit fee.

The Athyrium Credit Agreement was amended numerous times with the Company paying various financing costs, incurring costs to record and subsequently to adjust the value of warrants issued to Athyrium (see note 10) and accreting the exit fee described above. These costs were recognized in interest expense using the effective interest method over the term of the Athyrium Credit Agreement, resulting in non-cash interest expense of $4,411 in 2022, $5,558 in 2021 and $5,510 in 2020. As a result of fully paying off the terms loans under the Athyrium Credit Agreement, the Company recorded a loss on extinguishment of debt of $4,996 for the write-off of the remaining unamortized deferred financing costs.

The overall effective interest rate, including cash paid for interest and non-cash interest expense, immediately prior to repayment was 16.4%.

Note with former equity holder of IriSys

In connection with the acquisition of IriSys (see note 15), the Company issued a subordinated promissory note to a former equity holder of IriSys in the aggregate principal amount of $6,117 (the "Note"). The Note is unsecured, has a three-year term, and bears interest at a rate of 6% per annum. The Note must be repaid in three equal annual installments through its maturity date, August 13, 2024. The Note may be prepaid in whole or in part at any time prior to the maturity date. The Note is expressly subordinated in right of payment and priority to the term loan under the Credit Agreement with Royal Bank of Canada.

The Note was initially recognized at fair value as part of the consideration paid for the acquisition of IriSys, resulting in an original discount recognized of $877 that is being recognized as interest expense using the effective interest method over the term of the Note. At December 31, 2022, the overall effective interest rate, including the amortization of the original discount, was 13.0%.

The Company paid interest of $367 to the note holder during the year ended December 31, 2022 and has accrued interest of $94 in 2022 that will become payable to the former equity holder of IriSys on August 13, 2023.

Other

In connection with the acquisition of IriSys (see note 15), the Company assumed a loan with a principal amount of $339.

In May 2020, the Company entered into a $4,416 promissory note issued under a Federal COVID-19 relief program and shortly after prepaid $1,100 of principal to comply with emerging Federal guidance. The note had a two-year term and accrued interest at a rate of 1.0% per annum, payable upon maturity. In June 2021, the Company received forgiveness of principal and interest on the note and recorded a gain on extinguishment of debt of $3,352, consisting of forgiveness of $3,316 of principal and $36 of accrued interest.

(9) Other liabilities

At December 31, 2022, other liabilities include a sale-leaseback liability of $38,168 and other liabilities of $1,057.

Sale-leaseback liability

In December 2022, the Company concurrently entered into sale and lease agreements with Tenet Equity Funding SPE Gainesville, LLC ("Tenet") related to its commercial manufacturing campus in Gainesville, Georgia. The selling price was $39,000, of which $1,750 was retained by Tenet as a lease deposit and classified within other assets, resulting in cash proceeds to the Company of $37,250 in 2022. The lease is for an initial term of 20 years with four renewal options of ten years each. Rent under the lease will be payable monthly at a rate of $3,510 per year, increasing annually by 3%, except for the first year where annual base rent will increase by the change in the consumer price index, not to exceed 5%, if greater. The Company is responsible for the payment of all operating expenses, property taxes and insurance for the property. Pursuant to the terms of the lease, the Company will have a purchase option every ten years and a right of first offer and a right of first refusal to purchase the property should the buyer-lessor intend to sell the property to a third party.

The Company determined that it did not relinquish control of the assets to the buyer-lessor. Therefore, the assets were not derecognized, and the selling price was recorded as a financial liability. As of December 31, 2022, the Company has recognized a liability of $38,168, that is net of $869 of deferred financing costs. The Company will recognize interest expense at a 10.95% imputed rate of interest over a term of 20 years. The deferred financing costs will also be amortized and recognized as interest expense using the effective interest method over the term of the lease. The gross liability balance will increase through 2034, at which point it will decrease through the end of lease term on December 31, 2042.

(10) Shareholders' equity or deficit

Convertible preferred stock

In December 2022, the Company issued 450,000 shares of Series A Convertible Preferred Stock for proceeds of $11.00 per share. Each share is convertible into ten shares of common stock automatically upon approval by the Company's shareholders to increase the number of authorized shares of common stock. If the approval is not obtained by June 30, 2023, the conversion rate will be immediately increased by 10% and annually thereafter until approval has been obtained. Shares of Series A Convertible Preferred Stock feature a liquidation preference over common shares, have no voting rights and are entitled to receive dividends equally with shares of common stock on an as-if-converted basis.

Warrants

At December 31, 2022, warrants to purchase 402,126 shares of common stock were outstanding. The warrants are held by Athyrium, equity-classified, exercisable at $1.50 per share and expire in November 2024. See note 8 for additional details.

(11) Revenue recognition

The following table presents changes in contract assets and liabilities:

	Contract assets	Contract liabilities
Balance at December 31, 2021	$ 8,565	$ (2,308)
Changes to the beginning balance arising from:		
Reclassification to receivables as the result of rights to consideration becoming unconditional	(11,298)	—
Reclassification to revenue as the result of performance obligations satisfied	1,078	2,022
Changes in estimate	1,869	17
Net change to contract balance recognized since beginning of period due to recognition of revenue, amounts billed and changes in estimate	8,510	(1,942)
Balance at December 31, 2022	$ 8,724	$ (2,211)

Contract assets and contract liabilities are reported at the contract level. Contracts with multiple performance obligation are reported as a net contract asset or contract liability on the consolidated balance sheet. The reclassification to revenue appearing in the contract assets column results from the recognition of revenue on contract liabilities that are presented as a net contract asset at the beginning of the year.

The following table disaggregates revenue by timing of revenue recognition:

	Year ended December 31,		
	2022	2021	2020
Point in time	$ 70,325	$ 60,992	$ 61,616
Over time	19,889	14,368	4,883
Total	$ 90,214	$ 75,360	$ 66,499

The Company's payment terms for manufacturing revenue and development services are typically 30 to 45 days. Profit-sharing revenue is recorded to accounts receivable in the quarter that the product is sold by the commercial partner upon reporting from the commercial partner and payment terms are generally 45 days after quarter end.

(12) Retirement Plan

The Company has a voluntary 401(k) savings plan in which all employees are eligible to participate. The Company's policy is to match 100% of the employee contributions up to a maximum of 5% of employee compensation. Total Company contributions to the 401(k) plan were $1,348 for 2022, $915 for 2021 and $941 for 2020.

(13) Stock-based compensation

In October 2013, the Company established an equity incentive plan that has been subsequently amended and restated to become the 2018 Amended and Restated Equity Incentive Plan (the "A&R Plan"). At December 31, 2022, a total of 3,237,642 shares were available for future grants under the A&R Plan. On December 1st of each year, pursuant to an "evergreen" provision of the A&R Plan, the number of shares available under the A&R Plan may be increased by the board of directors by an amount equal to 5% of the outstanding common stock on December 1st of that year.

Stock options

Stock options are exercisable generally for a period of ten years from the date of grant and generally vest over four years.

The following table presents information about the fair value of stock options granted:

	Year ended December 31,		
	2022	2021	2020
Weighted average grant date fair value	$ 1.02	$ 1.77	$ 5.14
Assumptions used to determine fair value:			
Range of expected option life	5.5 - 6.0 years	5.5 - 6.0 years	5.5 - 6.0 years
Expected volatility	79 - 81%	79 - 81%	75 - 81%
Risk-free interest rate	1.5 - 4.0%	0.7 - 1.4%	0.3 - 1.4%
Expected dividend yield	—	—	—

The intrinsic value of options exercised were negligible in 2022 and 2021, and $1,058 in 2020.

The following table presents information about stock option balances and activity:

	Number of shares	Weighted average exercise price	Aggregate intrinsic value	Weighted average remaining contractual life
Balance, December 31, 2021	5,267,567	$ 6.47		5.7 years
Granted	4,055,633	1.49		
Exercised	(516)	1.32		
Exchanged	(668,009)	9.79		
Forfeited or expired	(604,338)	3.75		
Balance, December 31, 2022	8,050,337	3.89	$ —	6.6 years
Exercisable	4,054,697	6.01	—	4.4 years

Included in the table above are 1,210,552 options outstanding as of December 31, 2022 that were granted outside the A&R Plan. The grants were made pursuant to the inducement grant exception in accordance with Nasdaq Listing Rule 5635(c)(4).

The Company issued an offer to certain employees to cancel options that met defined eligibility requirements in exchange for RSUs. Pursuant to the exchange offer, the Company cancelled 668,009 stock options and granted 167,094 RSUs that will vest in two equal annual installments.

Restricted stock units

Restricted stock units ("RSUs") vest over six months to four years depending on the purpose of the award and sometimes include performance conditions in addition to service conditions. The fair value of RSUs on the date of grant is measured as the closing price of the Company's common stock on that date. The weighted average grant-date fair value of RSUs awarded to employees was $1.32 in 2022, $3.49 in 2021 and $5.34 in 2020. The fair value of RSUs vested was $897 in 2022, $2,663 in 2021 and $4,039 in 2020.

The following table presents information about recent RSU activity:

	Number of shares	Weighted average grant date fair value
Balance, December 31, 2021	990,065	$ 3.63
Granted	1,552,590	1.32
Exchanged	167,094	0.80
Vested	(587,895)	3.56
Forfeited	(59,988)	2.44
Balance, December 31, 2022	2,061,866	1.71

Included in the table above are 77,256 time-based RSUs outstanding at December 31, 2022 that were granted outside of the A&R Plan. The grants were made pursuant to the inducement grant exception in accordance with Nasdaq Listing Rule 5635(c)(4).

Other information

The following table presents the classification of stock-based compensation expense:

	Year ended December 31,		
	2022	2021	2020
Cost of sales	$ 1,868	$ 2,797	$ 3,754
Selling, general and administrative expenses	3,558	3,717	6,314
Total	$ 5,426	$ 6,514	$ 10,068

For the year ended December 31, 2020, stock-based compensation expense included awards issued to the Company's employees as well as Baudax Bio employees that provided services to the Company through the transition services agreement and certain other related agreements. In accordance with the terms of those agreements, the Societal equity grants held by such former employees continued to vest in accordance with their respective vesting schedules. Any stock-based compensation expense with respect to former employees who continue to vest based on their employment service at Baudax Bio but no longer provide services to the Company is not reflected in the Company's financial statements.

As of December 31, 2022, there was $7,108 of unrecognized compensation expense related to unvested options and RSUs that are expected to vest and will be expensed over a weighted average period of 2.1 years.

(14) Income Taxes

All of the Company's income from continuing operations is domestic. The components of the income tax provision from continuing operations are as follows:

	Year ended December 31,		
	2022	2021	2020
Current:			
Federal	$ 33	$ —	$ —
State	57	—	—
Total current	90	—	—
Deferred:			
Federal	1,399	(2,396)	(5,539)
State	4,266	(677)	(1,596)
Total deferred	5,665	(3,073)	(7,135)
Change in valuation allowance	(4,650)	3,073	7,135
Income tax expense	$ 1,105	$ —	$ —

In 2022, the Company entered into a sale-leaseback transaction of its commercial manufacturing campus in Gainesville, Georgia, as discussed further in note 9. This transaction was treated as a sale for federal and state income tax purposes. The sale resulted in a taxable gain of approximately $25,350 that was mostly offset with net operating loss carryforwards, as discussed further below. Following application payments made in 2022, of net operating loss carryforwards and other tax attributes, the Company estimates a current tax obligation of $47 for tax year 2022, which is included in accrued expenses and other current liabilities on the consolidated balance sheet. The Company also recognized a deferred tax provision of $1,015 as discussed further below.

A reconciliation of the statutory U.S. federal income tax rate to the Company's effective tax rate is as follows:

	Year ended December 31,		
	2022	2021	2020
U.S. federal statutory income tax rate	21%	21%	21%
State taxes, net of federal benefit	7%	8%	6%
Change in state tax rate	(22)%	(2)%	—
Nondeductible expenses	(5)%	(1)%	(1)%
Research and development credits	(23)%	1%	—
Change in valuation allowance	16%	(27)%	(26)%
Other	—	—	—
Effective income tax rate	(6)%	—	—

In 2022, the Commonwealth of Pennsylvania enacted a reduction to its corporate tax rate from 9.9% to 8.9% in 2023. Additionally, the rate will be further reduced by 0.5% each year until 2031 when the rate will be 4.99%. This resulted in a revaluation of outstanding state deferred taxes and the significant rate change above. In 2022, the Company also derecognized its deferred tax assets for research and development credits as discussed further below.

The tax effects of temporary differences that gave rise to significant portions of the deferred tax assets were as follows:

	December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 33,352	$ 38,970
Interest expense	12,944	13,960
Sale-leaseback	9,093	—
Stock-based compensation	4,681	4,459
Research and development credits	—	4,581
Other	3,950	4,635
Gross deferred tax asset	64,020	66,605
Valuation allowance	(50,909)	(55,421)
Deferred tax assets, net of valuation allowance	13,111	11,184
Deferred tax liabilities:		
Depreciation	(10,750)	(7,057)
Contract assets	(2,082)	(2,346)
Other	(1,294)	(1,781)
Deferred tax liabilities	(14,126)	(11,184)
Net deferred tax liabilities	$ (1,015)	$ —

The net deferred tax liability shown in the table above is recorded in other liabilities on the consolidated balance sheet at December 31, 2022. These net liabilities result from future tax years in which settlements of deferred tax liabilities are forecasted to exceed settlements of deferred tax assets. Beginning December 31, 2022, net operating loss carryforwards that could fully offset such liabilities are no longer available because they were all utilized for the December 2022 sale-leaseback transaction, as discussed further below.

The Company continues to maintain a full valuation allowance against its U.S. and state deferred tax assets based on the available positive and negative evidence available. An important aspect of objective negative evidence evaluated was the Company's historical operating results over the prior three-year period. The Company maintains the valuation allowance as of December 31, 2022 as a result of historical losses, inclusive of discontinued operations, during the most recent three-year period. The Company will re-evaluate the need for a valuation allowance in future periods based on its operating results as a standalone entity.

The following table summarizes carryforwards of net operating losses as of December 31, 2022:

	Amount	Expiration
Federal net operating losses, 2008 to 2017	$ 76	2028
Federal net operating losses, 2018 to 2022	125,501	No expiration
State net operating losses	135,420	2028 – 2042

Under U.S. federal tax law, the utilization of a corporation's net operating loss and research and development tax credit carryforwards is limited following a greater than 50% change in ownership during a three-year period. Any unused annual limitation may be carried forward to future years for the balance of the carryforward period. The Company has determined that it experienced ownership changes, as defined by the Act, during the 2008, 2014, 2016 and 2022 tax years; accordingly, the Company's ability to utilize the aforementioned carryforwards is subject to various annual limitations. As a result of the 2022 ownership change, the Company further determined its research and development tax credits would not be available in future periods, so the related deferred tax assets were written off in 2022. State net operating loss carryforwards may be further limited, including in Pennsylvania, which has a limitation of 40% of taxable income after modifications and apportionment on state net operating losses utilized in any one year.

At December 31, 2022, the Company had no accrued interest or penalties related to uncertain tax positions, and no amounts have been recognized in the Company's statements of operations. Due to net operating loss and tax credit carry forwards that remain unutilized, income tax returns for tax years since inception remain subject to examination by the taxing jurisdictions.

(15) Acquisition of IriSys

On August 13, 2021, the Company acquired all of the units of IriSys pursuant to a unit purchase agreement. IriSys provides contract pharmaceutical product development and manufacturing services, specializing in formulation research and development and good manufacturing practices of clinical trial materials and specialty pharmaceutical products. The acquisition advances the Company's ongoing growth strategy and leads to key synergies within business development, clinical development and commercial scale-up, as well as a strong cultural alignment and fit between the companies.

The aggregate purchase price consideration was comprised of cash consideration, a subordinated promissory note and a contractual obligation to issue 9,302,718 shares of the Company's common stock, which were issued on February 14, 2022. The following table summarizes the consideration paid:

	August 13, 2021
Cash paid, net of cash acquired	$ 24,002
Net working capital adjustment receivable	(417)
Fair value of shares issuable to former equity holders of IriSys	20,931
Fair value of note with former equity holder of IriSys	5,240
Total estimated consideration	$ 49,756

The fair value of the shares issuable was determined by using the price of the Company's common stock on the acquisition date, less a discount for lack of marketability due to the shares being unregistered shares of the Company. The fair value of the note was determined using a discounted cash flow analysis that incorporated an estimate of the market interest rate for debt of similar terms and credit risk on the acquisition date.

The Company incurred $1,211 in transaction costs related to the acquisition that were expensed as incurred and classified as selling, general and administrative expenses.

The following table summarizes the fair values of the assets acquired and liabilities assumed at the date of acquisition:

	As of August 13, 2021
Assets acquired:	
Accounts receivable	$ 909
Contract assets	505
Inventory	685
Prepaid expenses and other current assets	91
Property and equipment	9,304
Operating lease asset	5,648
Intangible assets	4,170
Goodwill	36,758
Other assets	146
Total assets acquired	$ 58,216
Liabilities assumed:	
Accounts payable	$ 730
Accrued expenses and other current liabilities	1,556
Operating lease liability	5,648
Debt from finance loan	339
Other liabilities	187
Total liabilities assumed	$ 8,460
Net assets acquired	$ 49,756

The purchase price was allocated to the tangible assets and identifiable intangible assets acquired and liabilities assumed based on their acquisition date estimated fair values. The identifiable intangible assets are subject to amortization on a straight-line basis. The following table presents information about the acquired identifiable intangible assets:

	Fair value	Weighted average amortization period
Customer relationships	$ 3,400	7.0 years
Backlog	460	2.4 years
Trademarks and tradenames	310	1.5 years
Total	$ 4,170	6.1 years

The fair value of property, plant and equipment was determined using a cost approach valuation method. The customer relationships and acquired backlog were valued using the multi-period excess earnings method and trademarks and trade names were valued using the relief from royalty method. These methods require several judgments and assumptions to determine the fair value of intangible assets, including revenue growth rates, discount rates, EBITDA margins, and tax rates, among others. These nonrecurring fair value measurements are Level 3 measurements within the fair value hierarchy.

Goodwill represents the excess of the purchase price over the net identifiable tangible and intangible assets acquired. The goodwill related to the acquisition was attributable to expected synergies, the value of the assembled workforce as well as the collective experience of the management team with regards to its operations, customers, and industry. The goodwill is deductible for tax purposes.

Results for 2021 included revenue of $5,955 and net income of $440 from IriSys. The following table presents unaudited supplemental pro forma financial information as if the IriSys acquisition had occurred on January 1, 2020:

	Year ended December 31,	
	2021	2020
Revenue	$ 83,045	$ 78,881
Net income (loss)	(11,809)	(28,290)

The pro forma financial information presented above has been prepared by combining the Company's historical results and the historical results of IriSys and adjusting those results to eliminate historical transaction costs and to reflect the effects of the acquisition as if they occurred on January 1, 2020. The effects of the acquisition on the historical pro forma financial information include additional depreciation and amortization expense from the increase of asset carrying values to fair value, the adoption of new accounting standards, additional interest expense from the issuance of the subordinated promissory note and the elimination of interest expense related to indebtedness of IriSys prior to the acquisition. These results do not purport to be indicative of the results of operations which actually would have resulted had the acquisitions occurred on the date indicated above, or that may result in the future, and do not reflect potential synergies or additional costs following the acquisition.

(16) Fair value of financial instruments

The Company follows the provisions of FASB ASC Topic 820, "*Fair Value Measurements and Disclosures*," for fair value measurement recognition and disclosure purposes for its financial assets and financial liabilities that are remeasured and reported at fair value each reporting period. The Company measures certain financial assets and liabilities at fair value on a recurring basis, including cash equivalents, short-term investments and certain warrants. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the valuation of financial assets and financial liabilities and their placement within the fair value hierarchy. Categorization is based on a three-tier valuation hierarchy, which prioritizes the inputs used in measuring fair value, as follows:

- Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities;
- Level 2: Inputs that are other than quoted prices in active markets for identical assets and liabilities, inputs that are quoted prices for identical or similar assets or liabilities in inactive markets, or other inputs that are either directly or indirectly observable; and
- Level 3: Unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

Items measured at fair value on a recurring basis

Cash equivalents of $6,034 at December 31, 2022 and $15,247 at December 31, 2021 consisted entirely of money market mutual funds whose fair value were determined using Level 1 measurements.

Fair value disclosures

The Company follows the disclosure provisions of FASB ASC Topic 825, "*Financial Instruments*" (ASC 825), for disclosure purposes for financial assets and financial liabilities that are not measured at fair value. As of December 31, 2022, the financial assets and liabilities recorded on the consolidated balance sheets that are not measured at fair value on a recurring basis include accounts receivable, accounts payable and accrued expenses. The carrying values of these financial assets and liabilities approximate fair value due to their short-term nature.

The fair value of long-term debt, where a quoted market price is not available, is evaluated based on, among other factors, interest rates currently available to the Company for debt with similar terms, remaining payments and considerations of the Company's creditworthiness. The Company determined that the recorded book value of its debt, a level 2 measurement, approximated fair value at December 31, 2022 due to the recent issuances of those instruments and taking into consideration management's current evaluation of market conditions.

(17) Leases

The Company is party to two operating leases for development facilities in California and Georgia that end in 2031 and 2025, respectively, as well as other immaterial operating leases for office space, storage and office equipment. The development facility leases each include options to extend, none of which are included in the lease terms. Short-term and variable lease costs were not material for the periods presented. The development facility leases do not provide an implicit rate, so the Company uses its incremental borrowing rate to discount the lease liabilities.

Undiscounted future lease payments for the two development leases, which were the only material noncancelable leases at December 31, 2022, were as follows:

Twelve months ended December 31,		
2023	$	1,165
2024		1,193
2025		1,158
2026		1,097
2027		1,127
Thereafter		3,681
Total lease payments		9,421
Less imputed interest		(3,758)
Total operating lease liabilities	$	5,663

At December 31, 2022, the weighted average remaining lease term was 7.8 years, and the weighted average discount rate was 14.1%. Total lease cost was $1,980 in 2022, $814 in 2021 and $310 in 2020.

(18) Related Party Transactions

The former equity holder of IriSys beneficially owned more than 10% of the Company's common stock and became a related party on August 13, 2021 as a result of the acquisition of IriSys (see notes 10 and 15). In December 2022, it ceased to meet the definition of a related party following the issuance of additional common stock.